Department of Health and Human Services
Division of Licensing and Certification
State House, Augusta, Maine
Preliminary Analysis

Date: **March 5, 2021**

Project: **Central Maine Healthcare Construction of Ambulatory Surgical Center.**

Proposal by: **Central Maine Healthcare**

Prepared by: **Larry Carbonneau, Manager, Health Care Oversight**
Richard S. Lawrence, Senior Health Care Financial Analyst

Directly Affected Party: Mid Coast – Parkview Health

CON Recommendation: Denial

	Proposed Per Applicant	CON Adjustment	Approved CON
Estimated Capital Expenditure	$ 15,428,927		$0
Maximum Contingency	$ 1,050,000		$0
Total Capital Expenditure with Contingency	$ 16,478,927		$0
Pro-Forma Marginal Operating Costs	$ 5,488,000		$0

Contents

Certificate of Need Purpose:

The Legislature finds that unnecessary construction or modification of health care facilities and duplication of health services are substantial factors in the cost of health care and the ability of the public to obtain necessary medical services.

A. Support effective health planning.

B. Support the provisions of quality health care in a manner that ensures access to cost-effective services.

C. Support reasonable choice in health care services while avoiding excessive duplication.

D. Ensure that state funds are used prudently in the provision of health care services.

E. Ensure public participation in the process of determining the array, distribution, quantity, quality and cost of these health care services.

F. Improve the availability of health care services throughout the State.

G. Support the development and availability of health care services regardless of the consumer's ability to pay.

H. Seek a balance, to the extent a balance assists in achieving the purposes of this subsection, between competition and regulation in the provision of health care.

I. Promote the development of primary and secondary preventive health care services.

I. Abstract

A. From Applicant

Project Overview

Central Maine Healthcare Corporation and its affiliates (CMHC) propose to build a freestanding ambulatory surgical center in Topsham (the Topsham ASC) to provide new treatment capabilities, operational efficiencies, improved access, and a safe, high quality patient experience. The Topsham ASC is necessary in order to meet the projected organic growth in outpatient surgical services in the area and provide a missing component of care in the specialty services CMHC currently provides in Topsham. CMHC has provided physician office-based services in Topsham for over a decade and currently provides physician services that include the following key specialties: gastroenterology, orthopedics, cancer care, urology, and ear nose and throat (ENT). CMHC proposes to build two operating rooms and four procedure rooms to offer outpatient surgical services in gastroenterology, orthopedics, breast reconstruction, urology and ENT. This project is estimated to cost $14.2 Million and, subject to regulatory approval, construction is scheduled to commence by the Spring of 2021 with a scheduled opening by the Summer of 2022.

Currently, the southern mid-coast market lacks a low-cost option for low acuity surgical services in the market. The Topsham ASC will improve access to outpatient surgical services in the lowest cost care setting generally available for the proposed services. Increasingly, low acuity surgical services are being performed in freestanding ASC facilities. This shift towards an ASC setting reflects both national and state trends towards a more affordable care setting. ASCs also offer high quality services often achieving higher quality metrics than hospitals and are generally the lowest cost option. In addition, as highlighted by the COVID-19 pandemic, a freestanding ASC affords flexibility to the larger health care delivery system by providing an alternative treatment setting that allows patients to be treated safely and effectively.

CONU Comment #1:
This transaction is subject to Certificate of Need (CON) review per MRS Title 22, Chapter 103-A §329 (4-A). A certificate of need from the department is required for: Capital expenditures in excess of $3,000,000 (2020 threshold).

CONU Comment #2:
Centers for Medicare & Medicaid Services (CMS) defines an Ambulatory Surgical Center as a distinct entity that operates exclusively to furnish outpatient surgical services to patients who do not require hospitalization and are typically discharged less than 24 hours following admission. Medicare ASC patients should not need active medical monitoring at midnight on the day of the procedure. CMS recognizes Medicare participating ASCs as those that meet certification requirements and enter a legal agreement with them according to 42 Code of Federal Regulations (CFR) § 416 Subpart B (General Conditions and Requirements) to get Medicare payment. An

ASC can be Independent (not part of a provider of services or any other facility) or Operated by a hospital (under the common ownership, licensure, or control of a hospital), if it meets all of the following conditions

1): Be a separately identifiable entity, separately certified and enrolled in Medicare with a supplier approval and agreement distinct from the hospital's Medicare provider agreement.

2): Be physically, administratively, and financially independent and distinct from other hospital operations.

3): Treat ASC costs as a non-reimbursable cost center on the hospital's cost report.

4): Agree to the same assignment, coverage, and payment rules applied to independent ASCs.

5): Be surveyed, approved, and comply with the ASC conditions for coverage in 42 CFR §416 Subpart C.

CONU Comment #3

The applicant provided the following information in response to CONU requests for additional information:

CONU: Is this project an affiliation with another partner such as Spectrum Healthcare Partners? If so, please provide details regarding the association and responsibilities of each partner.

Applicant: This project is not an affiliation with another partner such as Spectrum Healthcare Partners. Central Maine Healthcare Corporation ("CMHC") will be the sole member of the Topsham ASC. CMHC will, however, use the experience it has gained from working with Spectrum Healthcare Partners and its experience providing outpatient surgical services more generally to develop and operate the Topsham ASC.

CONU: Is this a for-profit venture that will fall under Central Maine Health Ventures, Inc. on CMHC's financial statements or is this a non-profit?

Applicant: The Topsham ASC will not be a subsidiary of Central Maine Health Ventures, Inc., a for profit corporation. The Topsham ASC will be a Maine Limited liability company whose sole corporate member will be CMHC, a Maine nonprofit corporation. As a wholly owned subsidiary of CMHC, the Topsham ASC will be a disregarded entity for federal income tax purposes and will be part of the consolidated financial statement of its sole member, CMHC.

CONU: Please provide any details regarding CMHC's agreement with the developer including the name of the developer, financial and lease terms.

Applicant: CMHC will partner with a developer, Bateman Partners, to construct the proposed Topsham ASC. The plan of finance for the project involves developer financing of the facility

construction costs and long-term building lease by the developer to CMHC. These terms, accompanying operating and capital costs, projected volumes and proposed rates have been incorporated into the financial pro forma.

CONU Comment #4

In accordance with 22 M.R.S.A §339 (2), a virtual public hearing was held on July 22, 2020 to allow the applicant, other directly affected persons and the public to have an opportunity to present information, documentary evidence, arguments, and comments regarding this proposal. The transcript of this hearing and other written comments submitted to the Certificate of Need Unit are on file. Comments by the directly affected party be summarized in applicable sections of the preliminary analysis (the entirety of directly affected party comments are available at CONU). Public Comments received as a result of July 2020 virtual public hearing are on file at CONU and summarized below as For, Against or Neutral:

Date Received	For
Email 08/04/2020	High Quality, Cost effective, Access
Email 08/04/2020	Enhanced access to care, lower cost, state of the art facility
Email 08/04/2020	Access, Affordability, Alternatives, Convenience
Email 08/04/2020	Lower cost structure, Meets need for breast surgeries, convenient, Higher patient satisfaction, lower infection rates, greater efficiency
Email 07/24/2020	Competition will lower costs. Mid Coast Parkview is monopoly
07/20/2020	Extends CMHC's existing services, need surgical care closer to Topsham to eliminate need to travel, would serve a demonstrated need and avoid duplicate services in the Mid-Coast
07/20/2020	Services need to move outside walls of hospital, less risk of infection in ASC, improve access, cost effective
Email 07/22/2020	Larger tax base, quality jobs, provides service to community
Email	Access to care, quality, cost efficient
06/13/2020	Cost effective access, timely and responsive care, efficient
07/06/2020	Extension of CMHC's existing care in Topsham area, quality and efficient surgical services at lower cost
07/02/2020	Affordable, high quality option, transitional innovation
05/22/2020	More access to high quality, cost-effective healthcare, increase the availability of endoscopic procedures to detect cancers and abnormalities.

Email	ASC would provide access to safe, high-quality and affordable care
Email	Availability and access to services, quality
Email	High Quality Care, Affordable Care, Access to Care
Email	ASC's provide convenient, high quality, low cost care
06/11/2020	Convenient, High Quality, Low Cost Care
Email	Competition will lower costs. Merger of hospitals in the area have not lowered costs as expected.
Email 08/18/2020	ASC will satisfy demand for high quality care in a less-expensive, more convenient setting. Project will improve access to care.
Email 08/17/2020	Need other options in Brunswick area other than Mid Coast.
Email 08/17/2020	Significant economic benefits to Topsham. Increase access to high quality, cost effective care in the region.
08/18/2020	Self-insured company. Competition drives up quality of care and lowers costs.
08/18/2020	Self-insured company. Greater access to care and quality. Competition drives up quality of care and lowers costs.
08/18/2020	Promoting competition saves money. ASC patients have flexibility. Patients not limited to CMC providers. This project will improve value for patients.
08/18/2020	ASC provides positive and low- cost patient experience.
8/18/20 email	Would support patients and primary care, improve patient experience, improve the quality of care, and reduce cost
8/20/20 email	CMHC would provide extraordinary cost- effective price point and successfully collaborated as an ultra-efficient facility
8/20/20 email	The new facility will give residents the ability to receive more advance medical care in their own community, at an affordable cost.
8/20/20 email	This will be a much - needed addition to healthcare options in our area, options that until recently have been sorely lacking
8/20/20 email	CMHC already provides some services in Topsham and would be an incredible boon to people who live in that area
Email 8/21/2020	More options for care at an affordable price. Access close to home.

Email 8/21/2020	Lower cost options and local availability. High quality local development.
Email 8/21/2020	Lower cost and easier access to services in MidCoast.
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Ease of access, quality patient care at lower prices.
Email 8/21/2020	CMHC has history of providing care in the area. Provide high quality, low cost care. Project expands access to care.
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Innovative outpatient care will make health care more affordable. Competition and choice are important.
Email 8/21/2020	Project would address limited health care options. Expands options which would eliminate delays in care. Free standing rates, state of the art options and high quality.
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Low cost, convenient access to health care attracts employees and spurs economic development. Natural extension of existing medical facilities in the area.
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Cost efficient care is necessary for seniors.
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
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Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Critical need for convenient, low-cost, high quality care.
Email 8/21/2020	Received excellent care at CMHC for a breast care diagnosis. Care received at Mid Coast was inferior.
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience

	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Family has received good service at CMH run urgent care.
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	High quality care, low cost services, enhanced access.
Email 8/21/2020	Need affordable options in the market. Rates are lower at outpatient surgical site. Quality is high.
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Low cost, accessibility, quality, safety and convenience
Email 8/21/2020	Many clinical reasons why it is better to receive service at an ASC. Provides value- based care. Enhance patient access to care.
Email 8/21/2020	Positive economic development. Access to high-quality, cost effective care.
Email 8/21/2020	Cost of healthcare is challenging. Employees have had great success with CMHC. Access to healthcare is important.
Email 8/21/2020	Outpatient care at freestanding rates. Would lower healthcare costs in the region and would meet future demand.
08/21/2020 email	would provide those in Midcoast region with more advance care and connection to their own doctors. Also poised to increase access and accessibility to healthcare in that region
08/21/2020 email	The project allows the hospital system to focus on providing high quality service & care without being distracted by putting money into bricks & mortar infrastructure.
08/21/2020 email	Supports the expansion of cost- effective medical services and will be a strong boost to the town
8/21/20 email	In favor of approving this project to maintain a semblance of consumer choice in the market.
8/21/20 email	Will be a great addition to the community. Will be a benefit to the local economy. It will create new employment opportunities and many patients to Topsham's Downtown
Email 8/21/2020	ASC is new level of low cost and convenient healthcare. Low cost, convenience and quality of care are important drivers for patients. ASC would bring advance screening procedures into the area which prevents more serious illness.

Email 8/21/2020	CMHC has history of providing care in the area. Provide high quality, low cost care. Project expands access to care.

Date Received	Against
07/24/2020	Project only benefits CMHC's bottom line. Needs are already met by Mid Coast Hospital
08/04/2020	Small population base doesn't need new surgical center.
08/04/2020	CMHC will disrupt local healthcare. Project will only boost revenue for CMMC.
08/04/2020	Mid Coast only has 50% utilization. Local communities already served by existing facilities.
Email 08/03/2020	Duplication of services. ASC will impact Mid Coasts ability to help the underserved by diverting profitable patients away.
Email 07/28/2020	Duplication of services will not reduce costs, improve quality or increase access.
07/31/2020	ASC unnecessary. Existing surgical capacity is sufficient.
07/31/2020	ASC is a duplication of Services. Mid Coast is low cost provider.
07/31/2020	Duplication of Services. Mid Coast surgical services at 50% utilization.
07/23/2020	Community already has access to high quality, affordable surgical care. New ASC would duplicate services, waste resources and increase cost.
07/29/2020	ASC is not needed it exceeds capacity needs in community. The $14,000,000 facility will not lower costs. Inefficiencies in the marketplace such as duplicate services must be eliminated in order to lower overall costs.
07/29/2020	ASC would siphon resources from Mid Coast. Ambulatory surgical utilization at Mid Coast is at 50%.
07/30/2020	Existing capacity at Mid Coast is sufficient. Mid coast is a low-cost hospital. Mid Coast is a top performer in many key quality measures.
07/30/2020	Existing facilities in the area already provide care.
07/30/2020	ASC is being built to enhance CMMC's financial wellbeing.
07/29/2020	ASC would provide redundant services and would negatively impact Mid Coast financially and hurt their ability to provide excellent care.
Email 07/24/2020	Unnecessary ASC would cause costs to rise. Mid Coasts ability to provide free and uncompensated care would be compromised.
Email 07/25/2020	Mid Coast already has excess ambulatory surgery capacity and is in close proximity to Topsham. Health care cost will increase due to this proposal.

Email	CMHC should set up services where they are needed. Hospital needs resources to handle uncompensated care.
Email 07/17/2020	Mid Coast provides high quality low-cost care in a timely manner. There is a declining population in the area.
Email 07/18/2020	Free standing clinic will skim dollars away from full-service hospital that needs to treat all comers regardless of their ability to pay. The proposed ASC does not have to follow these laws.
Email 07/20/2020	Mid Coast has sufficient services. Mid Coast is a low-cost hospital.
Email 7/21/2020	No need for additional ambulatory surgery capacity. CMHC is attempting to increase its market share. ASC would impact finances of Mid Coast.
Email 07/21/2020	Duplicate services within 7 miles of each other. Oversupply of services would create negative consequences. A strong hospital is a cornerstone of a community.
Email 07/22/2020	ASC is being built to increase CMHC's revenue.
Email 07/23/2020	Small population base that wouldn't support another surgical center within 7 miles of hospital. High quality low-cost services are already available.
Email	Mid-Coast has an advances outpatient surgical center just a few miles away from the proposed ASC and the facility is at only 50% capacity. $14 million dollars to duplicate services is not necessary.
Email	Duplication of services. Additional services would negatively impact community by increasing costs for patients.
07/16/2020	ASC would only be 7 miles away from Mid Coast. Mid coasts costs are 30% lower than State average. ASC would add costs to health care system. Mid coast would be negatively impacted by ASC and would have to raise prices on services.
07/20/2020	Existing services are sufficient. The ASC would be a duplication.
07/23/2020	Building ASC would disrupt existing healthcare system that is already providing necessary services.
07/27/2020	Mid coast can take care of existing needs. Project would siphon off dollars from the hospital.
08/10/2020	Duplication of services
08/10/2020	Needs are already met. Duplication of services.
08/10/2020	Project only benefits CMHC's bottom line. Needs are already met by Mid Coast Hospital
08/10/2020	Duplication of services. Already have comprehensive healthcare delivery system

08/11/2020	Services already exist. Duplication of services. Mid Coast is a low-cost hospital.
08/11/2020	Specialty services in area siphon off services from Mid Coast. Mid Coast has capacity to meet needs.
08/11/2020	No waiting for services at Mid Coast. ASC would add additional overhead to healthcare infrastructure.
Email 08/11/2020	Duplication of services. Not enough demand.
Email 08/10/2020	Unhealth Competition. Uncalled for expenditures.
Email 08/10/2020	Duplication of services. Jeopardize solvency of Mid-Coast
Email 08/10/2020	No need for new surgical facility. Needs are already met. Financial stress on Mid Coast would result from this transaction.
Email 08/10/2020	Mid Coast does excellent job. Financial strain on Mid Coast.
Email 08/10/2020	Duplication of services. Continuum of care exists at Mid Coast.
Email 08/10/2020	Project would cannibalize patient load. Make both entities weaker. Overbuilding a cost-intensive operation is not in communities interest.
Email 08/10/2020	No need for new services.
Email 08/10/2020	Duplication. Underutilized surgical capacity. Excellent, low cost care is already provided by MidCoast.
Email 08/10/2020	Already multiple surgical choices in region.
Email 08/10/2020	Excess competition is already hurting Mid Coast. No need.
Email 08/09/2020	No need for additional surgical competition.
Email 08/09/2020	No need for project. Will harm local healthcare.
Email 08/09/2020	Project would hurt local healthcare and harm local economy.
Email 08/09/2020	Unnecessary ASC would harm existing services and hurt economy.
Email 08/09/2020	No need for project. Will harm local healthcare.
Email 08/09/2020	Hospitals working on small margin. ASC would further hurt this.

	Concerned about for-profit medical services hurting Mid Coast.
Email 08/09/2020	Would impact Mid Coasts ability to provide free and uncompensated care. Financial impact of ASC may force them to make cuts to services and staff. New surgical services aren't needed.
08/13/2020	Not enough population in region to support duplicate services. Duplicate services would result in cuts or increased prices at Mid Coast -Parkview
08/13/2020	Needs in area already met. New ASC would not be available 24-7 in the event of an emergency. Would shift profitable services away from Mid Coast - Parkview.
08/13/2020	Needs are being met with timely outpatient surgeries.
Email 08/14/2020	Healthcare needs are met. Duplicate services would add additional financial stress to hospitals already stressed by COVID-19.
Email 08/14/2020	Project is a duplication of existing capability.
Email 08/12/2020	Surplus capacity in the area. Additional competition would be harmful to Mid Coast - Parkview.
Email 08/15/2020	Excess surgical capacity would hurt Mid Coast. Should open ASC in part of the state that is underserved.
Email 08/15/2020	ASC would hurt Mid Coast financially and wouldn't provide 24/7 care should complications arise.
Email 08/15/2020	Already sufficient competition in the area. ASC will undermine the economics of Mid Coast in the long run. CMHC is poorly managed, overextended and clinically deficient organization.
Email 08/16/2020	Duplication of facilities is a waste of money. This project would result in significant idle time in duplicate facilities. Safety is key and when complications inevitably arise you need expertise to handle them.
Email 08/16/2020	ASC would compete with Mid Coast and compromise its financial stability.
Email	ASC would harm the local health care system.
email 8/17/20	CMHC proposal is not needed and would have negative effects on Brunswick, Topsham and surrounding communities
Email 08/17/2020	CMHC's service area is not the Mid-Coast. ASC duplicates existing services. Cherry picks profitable services without the burden of providing full array of necessary healthcare services.
Email 08/17/2020	Low population growth in service area. No unmet need for ASC to fill. ASC would need to take patients away from Mid Coast.
email 08/18/2020	With Mid Coast current ASC at 50% utilization, they are capable of meeting the community's needs now and in the future.

08/18/2020	Integration and coordination of care that takes place at Mid Coast is very important. ASC would undercut the effectiveness of the existing community health care system.
8/20/20 email	The economic and opportunity costs to our communities will be significant and enduring.
08/18/2020	No current or anticipated need for project. Resources should be used to support existing services.
08/18/2020	Needs are currently being met with existing facilities. Mid Coast and Parkview successfully consolidated services and the ASC would negate this.
08/18/2020	Would negatively impact overall healthcare system and vitality of MCPH
8/18/20 email	Mid Coast already performs all the procedures CMHC is proposing, Not needed.
08/18/2020	No justification for project because no need exists. Current capacity will meet current and future needs. Mid Coast is a low- cost provider.
8/19/20 email	The CON application fails the ethics test and hope's that the State will refuse CMHC's CON application and release Mid Coast to continue delivering excellence in holistic care
8/19/20 email	Has received timely, quality care at Mid Coast. Sees no reason to have an outlier building and unneeded facility
Email 8/21/2020	Unnecessary duplication is a bad business model.
08/21/2020 email	There is no need for CMHC to expand in Topsham with an ASC, as Mid-Coast already providing these services and quality care
Email 8/21/2020	No need for another facility. Would hurt Mid Coast/

Date Received Neutral

Email 08/05/2020	Must evaluate effect of project on delicate ecosystem of healthcare in the region.

Post Technical Assistance Meeting Additional Information:

In accordance with MRS Title 22, Chapter 103-A §335 (6) B. A technical assistance meeting with the department must be scheduled at least 10 days before the department publishes the preliminary analysis of a certificate of need application. At the technical assistance meeting the department gave applicants an opportunity to hear whether the certificate of need application is

likely to be approved or denied; gave applicants an opportunity to address issues and concerns expressed by the department regarding compliance with this chapter; and gave applicants an opportunity to offer additional information to the department. Any additional information submitted by the applicant becomes part of the public record. Additional information provided by the applicant included June 30, 2020 audited financial statements, Representative ASC Policies and Procedures and a 10-page written narrative to further address CON standards. CONU will include and provide responses, where necessary, to this information in the appropriate sections of this analysis. The department completed its review after the technical assistance meeting and before the department published the preliminary analysis.

Post Technical Assistance Meeting Additional Information - Narrative

Central Maine Healthcare Corporation's (CMHC) application for a freestanding Ambulatory Surgical Center (ASC) in Topsham, Maine (the Project), is a carefully designed and well-supported project that will provide access to something missing in Maine and the southern mid-coast region--convenient, low-cost, high quality surgical services. ASCs have been widely adopted across the nation to lower economic barriers to access to vital surgical services. The core assertion in the CMHC application is that the Project will fill the unmet and growing need for lower cost outpatient surgical services. This is a distinction that the directly affected party, $2.5+ billion MaineHealth, seeks to disregard by claiming that the only surgical services that should be provided in the region should be provided at MaineHealth's Brunswick hospital at higher costs than proposed by the Project.

MaineHealth is seeking to protect its lucrative pricing power in the southern mid-coast region and deny area residents a choice to seek convenient, high quality, low cost surgical care. MaineHealth does so by attempting to sow doubts about CMHC's intentions, motivations, and capabilities.

CMHC wishes to be clear about its rationale for and support of the Project:

- CMHC's *intention* is to provide the community, including its existing patients, with a choice for lower-cost access to outpatient surgical care.
- CMHC's *motivation* is to change the face of health care in Maine for the better. The State of Maine is the 9th highest in the U.S. for health care costs to employers, and 12th highest in the nation for health care costs to employees. This is unacceptable, unfair, and unsustainable for Mainers. CMHC is committed to employing best practices widely adopted across the country to positively impact this disparity.
- As to its capabilities, CMHC operates 16 surgery suites across three locations in Central and Western Maine. In a typical year, these operating rooms (ORs) are host to approximately 10,000 surgeries performed by our highly qualified specialists. Although MaineHealth claims that an outpatient procedure performed in an ASC OR is materially different than an outpatient procedure performed in a hospital OR, the procedures that would be performed at the Topsham ASC would be performed under the same rigorous

accreditation standards by the same surgeons and qualified support staff with the same oversight from CMHC regardless of location.

MaineHealth opposes the Project claiming dire financial consequences for its Brunswick hospital, yet the $2.5 billion system fails to acknowledge the outmigration that occurs once it acquires small hospitals in Maine. In addition, MaineHealth seems to ignore the importance and value of making available a variety of care settings for patients that include lower cost settings. Just as it is valuable to have a lower cost urgent care center to treat an ear infection after hours, the Topsham ASC would offer necessary outpatient surgical services like colonoscopies at a lower cost and in a more convenient setting. Urgent care centers will not replace emergency departments any more than an ASC will replace a hospital, but an ASC is a valuable setting for certain services and those services can be provided at a lower cost. CMHC's model with the Topsham ASC is to offer patients high quality care in the right setting at the right price. Finally, although all health systems have been challenged to respond to the COVID pandemic, the reality is that CMHC has experienced year-over-year improvement in its financial strength during the last three fiscal years. Through strategic use of developer financing for the non-core real estate investment component of the Project, CMHC will only make a small cash outlay to bring this high-value care option to the southern mid-coast community. CMHC's health system is focused on delivering clinical programs of excellence, exceptional patient experiences, and providing access to the right care at the right place, at the right price. This Project will hit all three of these objectives for the southern mid-coast community.

II. Fit, Willing and Able

A. From Applicant

Deeming Standard

This section is subject to a deeming standard. The Certificate of Need Act provides:

> If the applicant is a provider of health care services that are substantially similar to those services being reviewed and is licensed in the State, the requirements of this paragraph are deemed to have been met if the services previously provided in the State by the applicant are consistent with applicable licensing and certification standards.

22 M.R.S.A. § 335(7)(A). CMHC currently provides outpatient surgical services in hospital outpatient and ASC settings that are substantially similar to those services being reviewed, is fully licensed and provides outpatient surgical services consistent with applicable licensing and certification standards. Accordingly, CMHC should be deemed to be fit, willing and able to provide the proposed outpatient surgical services at the appropriate standards of care.

A. Profile of Applicant

The applicant for the Certificate of Need is CMHC, based in Lewiston, Maine. CMHC is a Maine nonprofit, 501(c)(3) tax-exempt corporation with a principal address at 300 Main Street, Lewiston, Maine 04240.

CMHC's core services network of affiliates includes one regional hospital (Central Maine Medical Center (CMMC)), two critical access hospitals (Bridgton Hospital and Rumford Hospital), an ambulatory surgery center, ambulatory care centers, population health management services, a reference laboratory, a retail pharmacy, and ground and air emergency transport services.

B. CMHC Affiliations

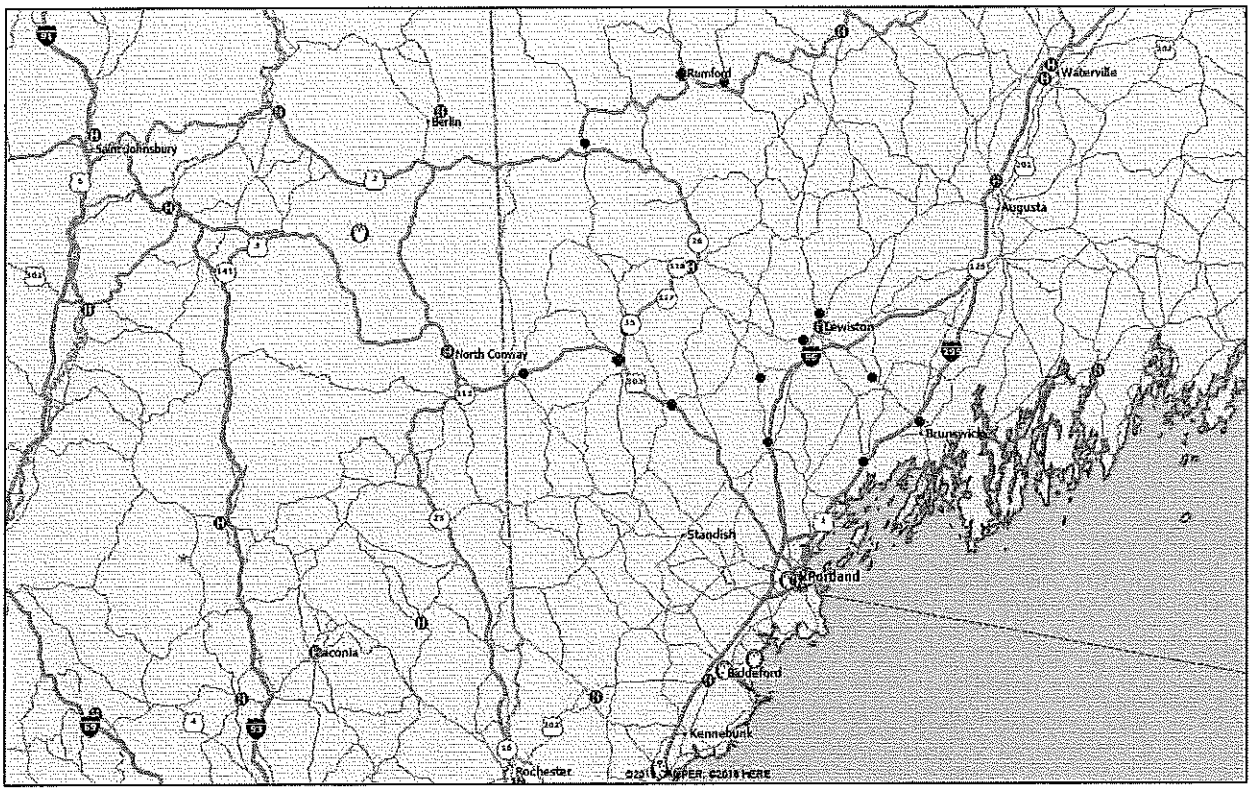
CMHC established an affiliation with Spectrum Healthcare Partners for the Central Maine Orthopaedics ASC in Auburn, Maine in 2018. CMHC has also been involved in an affiliation with Shields Healthcare, LLC since 2017.

C. Sites of Care

The sites of care map depicts the range and depth of CMHC's services across Maine (Figure 1). CMHC has developed an extensive provider network to provide inpatient, outpatient and post-acute care to a region comprised of 400,000 Maine residents. These sites of care include partial ownership in the Central Maine Orthopaedics ASC in Auburn, Maine.

CMHC performs outpatient surgical services at CMMC, Bridgton Hospital and Rumford Hospital in all services planned at the Topsham ASC. In addition, CMHC has partial ownership and performs outpatient orthopedic surgical services at the Central Maine Orthopaedics ASC in Auburn.

Figure 1: CMHCC Sites of Care. *Source: Central Maine Healthcare.*



D. Address

The address of the project will be adjacent to the existing CMHC Topsham Care Center at 105 Topsham Fair Mall Road, Topsham, Maine. This site will serve as an expansion of CMHC's historical presence in the southern mid-coast market where CMHC has provided primary care and specialty consultative services for over a decade.

E. CMHC System Development

CMHC began to undertake a financial turnaround in 2018. Consistent with broader industry trends and current trends in the State of Maine, CMHC is working to address cash flow pressures. The COVID-19 pandemic has amplified CMHC's cash flow pressures as elective procedures and surgeries have been suspended to protect the health and safety of CMHC's patients, providers, staff and the larger community.

In light of the foregoing, CMHC has evaluated, designed and implemented plans to reduce operating expenses. These plans focus primarily on a reduction in the utilization of premium contract labor expenses for locum tenens and nurse travelers. CMHC's management has incorporated into its performance expectations additional incremental operating improvements in fiscal year 2021 and has taken measures to reduce costs. As elective procedures and downstream volume recover from the COVID-19 pandemic, CMHC's management expects to return to normalized staffing and compensation levels.

While CMHC has experienced financial setbacks as a result of the COVID-19 pandemic, this project is expected to have a positive contribution margin towards CMHC's overall operational, fixed and overhead costs, thereby contributing to CMHC's profitability, liquidity and asset efficiency.

F. Mission, Vision and Values

Through collaboration with community organizations, independent physician groups, better coordination of care for patients and increased access, CMHC continues to shift to a value-based health care model in the State of Maine. As described herein, the proposed ASC will support and enhance CMHC's mission, vision, and values.

CMHC Mission

To provide exceptional health care services in a safe and trustful environment, through the expertise, commitment and compassion of our team of caregivers.

CMHC Vision

Safe, reliable, high-quality care of every patient, every day.

CMHC Values

Compassion, Citizenship, Integrity, Service, Excellence, Commitment

CMHC strives to make health care work for the people of Maine by providing high value, low cost health care. For example, all three of CMHC's hospitals hold 340b status and serve as disproportionate share hospitals (DSH) in the State. This project furthers CMHC's strategy to provide high value, low cost outpatient surgical services in the local community.

B. CONU Discussion

i. CON Standards

Relevant standards for inclusion in this section are specific to the determination that the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards. If the applicant is a provider of health care services that are substantially similar to those services being reviewed, and is licensed in the State, the requirements of this paragraph are deemed to have been met if the services previously provided in the State by the applicant are consistent with applicable licensing and certification standards.

ii. CON Analysis

Central Maine Healthcare (CMHC) is a Maine nonprofit, 501(c)(3) tax-exempt corporation based In Lewiston, Maine. CMHC is an integrated healthcare delivery system serving 400,000 people living in central, western, and mid-coast Maine. CMHC's hospital facilities include Central Maine Medical Center (CMMC) in Lewiston and 2 critical access hospitals located in Bridgton and Rumford. CMMC is a 250 -bed tertiary hospital with its' main campus located at 300 Main Street in Lewiston, Maine. CMMC is state licensed, Medicare and Medicaid certified, and Joint Commission accredited. CMHC also supports an ambulatory surgery center, ambulatory care centers, population health management services, and ground and air services and other clinical services.

The purpose of this project is to expand the range of specialty services already provided in the Topsham community to include surgical services. The project seeks to provide patients in the community with local access to a high quality, low cost surgical setting.

In order to determine if the applicant is fit, willing and able the CONU will utilize selected components of the four quality measures listed below for CMMC.

- Survey of patients' experiences
- Timely and effective care
- Complications and death
- Unplanned hospital visits

These quality measures are available at https://www.medicare.gov/hospitalcompare/search.html. CONU will summarize and analyze the latest data from the website. Data collected was from April 1, 2016 through September 30, 2019. (Data was downloaded from website –October 14, 2020).

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1.) Survey of patients' experiences:

Hospital Consumer Assessment of Healthcare Providers and Systems is a national survey that asks patients about their experiences during a recent hospital stay. The following chart summarizes results for CMMC and compares them to Maine and National averages.

PATIENT SURVEY RESULTS	CMMC	MAINE AVERAGE	NATIONAL AVERAGE
Patients who reported that their nurses "Always" communicated well	79%	84%	81%
Patients who reported that their doctors "Always" communicated well	81%	84%	82%
Patients who reported that they "Always" received help as soon as they wanted	62%	73%	70%
Patients who reported that staff "Always" explained about medicines before giving it to them	66%	70%	66%
Patients who reported that their room and bathroom were "Always" clean	68%	79%	76%
Patients who reported that the area around their room was "Always" quiet at night	46%	59%	62%
Patients who reported that YES, they were given information about what to do during their recovery at home	89%	89%	87%
Patients who "Strongly Agree" they understood their care when they left the hospital	51%	56%	54%
Patients who gave their hospital a rating of 9 or 10 on a scale from 0 (lowest) to 10 (highest)	66%	75%	73%
Patients who reported YES, they would recommend the hospital	68%	76%	72%

The patient survey results shown above indicate that CMMC scores below Maine averages in ten out of ten categories and above National averages in one of ten categories.

2.) Timely and Effective Care:

These measures show how often or how quickly hospitals provide care that research shows get the best results for patients with certain conditions. This information can help compare which hospitals give recommended care most often as part of the overall care they provide to patients. We looked at available data pertaining to cancer care, emergency department care, preventive care, blood clot prevention and medical imaging.

	CMMC	Maine Average	National Average
Cancer Care			
Percentage of patients receiving appropriate radiation therapy for cancer that has spread to the bone.	100%	83%	89%
Timely Emergency Dept. Care			
Percentage of patients who left the emergency dept. before being seen LOWER percentages are better	3%	2%	2%
Percentage of patients who came to the emergency department with stroke symptoms who received brain scan results within 45 min. of arrival HIGHER percentages are better	87%	63%	72%
Average (median) time patients	183	113	119

spent in the emergency dept., after the doctor decided to admit them as an inpatient before leaving the emergency dept. for inpatient room. LOWER number of min. is better			

Average (median) time patients spent in the emergency dept. before leaving from the visit LOWER number of min. is better	169	178	153

Preventive Care

Patients assessed and given influenza vaccination HIGHER percentages are better	99%	96%	93%

Healthcare workers given influenza vaccination HIGHER percentages are better	94%	90%	90%

Blood clot prevention

Patients who developed a blood clot while in the hospital who didn't get treatment that could have prevented it LOWER percentages are better	0%	2%	3%

Use of medical imaging

Outpatients with low-back pain who had an MRI without trying recommended treatments (like physical therapy) first (If a number is high, it may mean the facility is doing too many unnecessary MRI's for back pain)	36.6%	40.4%	39.0%

Outpatients who had a follow-up mammogram, breast ultrasound, or breasts MRI within the 45 days after a screening mammogram. (A follow-up rate near 0% may indicate missed cancer; a rate higher than 14% may mean there is unnecessary follow-up)	5.90%	6.80%	8.90%

Outpatient CT scans of the abdomen that were combination (double) scans (If a number is high, it may mean that too many patients have a double scan when a single scan is all they need.)	9.0%	4.0%	6.4%
Outpatient CT scans of the chest that were combination (double) scans (If a number is high, it may mean that too many patients have a double scan, when a single scan is all they need) LOWER percentages are better	0%	0.4%	1.4%
Outpatient who got cardiac imaging stress test before low risk outpatient surgery (If a number is high, it may mean that too many cardiac scans were done prior to low-risk surgeries)	4.6%	3.9%	4.2%
Outpatients with brain CT scans who got a sinus CT scan at the same time	1%	0.8%	1.2%

(If a number is high, it may mean that too many patients have both a brain and sinus scan, when a single scan is all they need)			

CMMC is consistent with Maine and National averages in most cases.

3). Complications and deaths:
Patients who are admitted to the hospital for treatment of medical problems sometimes get other serious injuries, complications, or conditions, and may even die. Some patients may experience problems soon after they are discharged and need to be admitted to the hospital again. These events can often be prevented if hospitals follow best practices for treating patients.

	CMMC	Maine Average	National Average
Surgical complications			
Rate of complications for hip/knee replacement patients	ND	NA	2.4%
Serious complications	ND	NA	1
Deaths among patients with serious treatable complications after surgery	ND	NA	164.15
30-day death rates			
Death rate for COPD patients	W	NA	8.4%
Death rate for heart attack patients	ND	NA	12.7%
Death rate for heart failure patients	ND	NA	11.3%

Death rate for pneumonia patients	ND	NA	15.4%
Death rate for stroke patients	W	NA	13.6%
Death rate for CABG surgery patients	ND	NA	3.%

B=Better, W = Worse, ND = No Different, NA = Not Available

CMMC scores no different than the National benchmark in seven instances and worse than the National benchmark in two instances.

4.) Unplanned Hospital Visits:
Returning to the hospital for unplanned care disrupts patients' lives, increases their risk of harmful events like healthcare associated infections, and costs more money. Hospitals that give high quality care can keep patients from returning to the hospital and reduce their stay if they must come back.

	CMMC	Maine Average	National Average
Rate of readmission for COPD patients	ND	NA	19.6%
Rate of readmission for heart attack patients	ND	NA	16.1%
Rate of readmission for heart failure patients	B	NA	21.9%
Rate of readmission for pneumonia patients	ND	NA	16.6%
Rate of readmission for coronary artery bypass graft surgery patients	ND	NA	12.7%
Rate of readmission after hip or knee replacement	ND	NA	4%

Rate of unplanned hospital visits after an outpatient colonoscopy	ND	NA	16.4%
Rate of readmission after discharge from hospital (hospital-wide)	ND	NA	15.6%

ND = no different than the National Rate. B = better than the National Rate. NA = not available

The results displayed above show that CMMC performed better than the national rate for unplanned hospital visits in 1 instance and no different than the national rate in 7 instances.

CONU also used the Hospital Compare website to get the overall rating of CMMC. CMMC received an overall rating of 2 out of 5 stars. This overall rating summarized up to 57 quality measures across seven areas of quality into a single star rating for each hospital. Hospitals report data to the Centers for Medicare & Medicaid Services (CMS) through the Hospital Inpatient Quality Reporting (IQR) Program and the Hospital Outpatient Quality Reporting (OQR) Program. The following table illustrates the national distribution of the overall star rating for the 4,573 participating hospitals:

National Distribution of Overall Star Ratings		
Overall Rating	Number of Hospitals	Percentage
5 stars	407	8.88%
4 stars	1138	24.82%
3 stars	1120	24.42%
2 stars	710	15.48%
1 star	228	4.97%
N/A	983	21.43%

The results above indicate that CMMC's 2- star rating put it in the bottom tier of national overall star ratings.

Survey Results

The results of the most recent surveys for CMMC are as follows:

Federal Survey

A Federal Hospital Validation Survey was conducted on February 11, 2015.

Federal Hospital Complaint

CMMC

A Federal Complaint investigation (#34618) was conducted on-site on 7/29/2020, 7/30/2020 and 8/6/2020. Off-site surveys were conducted on 7/31/2020 and 8/3 to 8/5/2020. This complaint investigation was conducted at CMMC to evaluate compliance with 42 Code of Federal Regulations, -§482.42 Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs.

This survey determined that the hospital was not in substantial compliance with 42 Code of Federal Regulation §482.12 Condition of Participation: Governing Body and §482.42 Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs. The identified non-compliance constituted a determination of IJ, beginning on 6/25/2020.

Based on document reviews, observations, and interviews, the hospital failed to implement strategies, including screening of visitors, patients, and employees , to prevent and control the transmission of COVID-19, to ensure employees wore a facemask within the hospital, and to ensure a clean and sanitary environment in the Intensive Care Unit (ICU). It was determined that these failures constituted an immediate jeopardy situation. Immediate jeopardy is defined as a situation in which a recipient of care has suffered or is likely to suffer serious injury, harm, impairment or death as a result of a provider's noncompliance with one or more health and safety requirements. See A-0749 and A-0750 for details.

The hospital was provided written notification (IJ template) on 8/6/2020 at 4:00 PM and placed on termination track with a termination date of 11/18/2020.

On 8/10/2020, surveyors verified that the hospital's plan to remove the IJ was implemented and was effective. The surveyors determined the abatement of the IJ by interviewing the Regulatory Compliance Coordinator, the Critical Care manager, the Chief Medical Officer (CMO) and an ICU Certified Nursing Assistant Technician regarding the process of ensuring screening employees, visitors and patients, and maintaining a clean environment on the ICU Unit; reviewing the completed screening documentation for 33 randomly selected employees from five different departments who worked since 8/9/2020; and observing employees maintaining compliance with facial coverings and limiting points of entry for employees. In addition, the CMO confirmed the process for surveillance and leadership involvement to ensure the Governing body is monitoring processes. CMMC provided a plan of correction on 8/26/2020.

On 9/17/2020 a revisit survey was conducted at CMMC. The revisit survey determined the hospital was back into substantial compliance with the Medicare requirements (regulations). On 9/18/2020, CMS sent the hospital a letter that officially notified them that they have returned to deemed status and are no longer under state survey jurisdiction.

In accordance with Title 22, Chapter 103-A §338 C. CONU consulted with licensing staff at the Division of Licensing and Certification regarding concerns about the quality of health care provided at CMHC. In the years 2018 through 2020 a total of 22 surveys were conducted at CMMC. Seven of these surveys resulted in deficiencies that included findings of regulatory violations. During the last three years, CMMC had the most surveys resulting in Condition-level deficiencies in the State for hospitals. As recently as August 2020, during the COVID-19 pandemic, CMMC failed to comply with CMS regulations regarding infection control placing

the health and safety of its patients at risk of serious illness, injury, harm, and/or impairment; and death. Included in the record is a March 1, 2019 Bangor Daily News article which mentioned that for the fourth year in a row CMMC received less funding from the federal Medicare program as a penalty of having high rates of infections and other patient complications.

CONU notes that the applicant has not operated an Ambulatory Surgical Center (ASC) in the past. Therefore, CONU cannot agree to consider this standard as deemed. The applicants have demonstrated their ability to operate a health care facility, but they have not demonstrated their ability to perform at a level consistent with licensing regulations at all times.

Directly Affected Party Comment:

CMHC claims it is fit, willing and able to operate the center, but in truth, the organization has no experience operating a free-standing surgical center. It cites its minority stake in an Auburn surgery center operated by Spectrum Medical Group, but it is merely an investor in that facility, not an operator. The application makes no mention of the unique requirements of providing surgical services without an adjacent hospital or emergency department or how CMHC would meet these requirements. It fails to even mention how it would staff such a facility at a time when surgeons and other specialized members of the care team are in short supply.

Operating a standalone ambulatory surgery center is different than operating an inpatient surgery suite or an ASU in a building attached to a hospital. The patient population is different. Patients eligible for procedures at an ambulatory surgery unit have fewer comorbidities and complications. Patients with comorbidities typically have procedures in an inpatient setting or near one. Inpatient settings provide a more advanced level of care capable of treating patients with comorbidities and complexities. CMHC has not demonstrated that they are fit and able to ensure that patients are appropriate for treatment at an ASC.

In addition to the differences within the patient population, managing the logistics and staffing schedules of a satellite surgical center are different than managing the logistics of a hospital surgery suite. Getting materials to and from the satellite center in an effective and cost-efficient way is a challenge with which CMHC is unfamiliar. Inventories of medications and supplies fluctuate based on need, and many of those materials have expiration dates which need to be considered when determining how much to have on hand and how to safely transport those materials if needed. Managing staffing patterns at a satellite center is also a task with which CMHC is unfamiliar. Staff must maintain the appropriate certifications to continue to provide care to patients. Many of those certifications require the staff member to have the appropriate experience and be exposed to care situations regularly. CMHC did not provide any information in their application to demonstrate that they can meet these challenges. CMHC does not provide a substantially similar service to those proposed and is not fit and able to operate the proposed free-standing surgical center.

In 2018, the ECRI Institute, an independent, nonprofit organization working to improve the safety, quality and cost effectiveness of care across all healthcare settings, expressed concern for the safety of freestanding ASCs as efforts to reduce payor costs – and presumably an interest in increasing profits – "have resulted in an increasingly long list of procedures that can now be

performed as outpatient operation."2 ECRI noted that "investigations also revealed that surgery centers have increasingly taken on risky procedures, and others may not spend sufficiently on training or equipment." *(Id.)* Risk managers were recommended to ensure that policies and procedures address areas of risk to patient safety that are common to inpatient surgery and anesthesia as well as *risks unique to ambulatory surgery...." (Id., emphasis added.)* CMHC has not demonstrated that it is fit and able to address the "risks unique to ambulatory surgery" at a freestanding ASC.

In 2009, the ECRI Institute was clear that the "challenge [of providing care in an ASC] is to ensure that patients undergo surgical procedures in the most appropriate setting. In light of this, risk managers must balance the need to maintain or increase revenues with the duty to ensure that safe, high-quality ambulatory surgical services are provided, regardless of the setting."3 Recognizing that providing healthcare in an ASC poses unique challenges, ECRI provides further: "Safe ambulatory surgery begins with appropriate patient screening and selection that includes an adequate history and physical examination. Patients with existing comorbidities often require laboratory and other diagnostic evaluation and monitoring before, during and after procedures involving the administration of anesthesia. Ambulatory surgery facilities must ensure that all providers and staff are properly trained to intervene in emergency situations, that emergency equipment and supplies are readily available and that emergency drills are carried out so that the team can practice its response to unanticipated events such as cardiac arrest. Credentialing and privileging of anesthesia providers should follow recommendations by ASA; quality and peer-review activities should include case evaluations for adherence to the standard of care."

CMHC claims that the ASC is a safer environment, but they fail to recognize the unique nature of the services provided at an ASC and they have not demonstrated that they are capable of determining when a patient can safely be treated at an ASC. They wish to be deemed capable but that would be improper. CMHC must show that they are capable. CMHC's application to spend nearly $15 million on the proposed ASC is devoid of any information from which the CON Unit can conclude that CMHC is fit and able to provide the proposed services.

Post Technical Assistance Meeting Additional Information -Fit, Willing and Able

ASCs have transformed the outpatient experience for millions of patients by providing them with a more convenient alternative to costly hospital-based outpatient procedures in a high quality, safe and convenient setting. ASCs treat only patients who have already seen a health care provider and only after that health care provider has selected surgery as the appropriate treatment for the patient's condition and determined that the surgery is appropriate for an ASC setting. This Project involves the development of 2 ORs and 4 procedure rooms to offer outpatient surgical services in gastroenterology, orthopedics, breast reconstruction, urology and ENT. CMHC performs outpatient surgical services at Central Maine Medical Center (CMMC), Bridgton Hospital and Rumford Hospital, including all of the services planned to be offered at the Topsham ASC.

Governance Structure, Oversight, and Standards to Ensure High Quality Care

The ASC will be a wholly owned subsidiary of CMHC, a tax-exempt, nonprofit corporation incorporated in the State of Maine. The ASC will have its own governing body that will oversee the ASC's operations, including peer review and credentialing at the ASC, and will ensure ASC providers have the necessary qualifications and skills to provide services. Physicians credentialed by the ASC will perform outpatient surgical services at the ASC and at other CMHC locations within the scope of their credentials and the privileges granted by the facilities at which they provide services and will include physicians that currently provide surgical services at CMMC, Bridgton Hospital and Rumford Hospital.

The Agency for Healthcare Research and Quality (AHRQ) has identified that the use of a consistent approach to quality and patient safety across a continuum of care in a health system is a key success factor to quality and patient safety. The ASC will participate in and utilize the expertise of the existing CMHC committees and departments for medical affairs, quality, risk management and infection prevention and apply the same robust clinical standards that are required in all of CMHC's ORs and procedure rooms. The ASC's operations will also be subject to CMHC system policies and procedures, including reporting to the Quality, Value and Community Health Committee of the Board of Directors of CMHC, to ensure all system level standards are applied to the ASC.

The ASC will meet all applicable licensure, accreditation and CMS conditions of participation standards. Attached as Appendix A is a comprehensive list of the policies and procedures required for the accreditation of an ASC. Examples of the standards CMHC already monitors for procedural facilities include measures such as the incidence of surgical site infections, surgical complications, transfers to higher levels of care, measures of high-level disinfection processes, penetrance of patient safety culture, patient experience scores, and provider and staff engagement scores.

In all cases, before care is provided at the ASC, the patient's provider must exercise his/her independent medical judgment to determine that care in an ASC setting is medically necessary and in the best interest of the patient, and the patient must choose to have the procedure performed at the ASC. CMHC will utilize the approaches taken by the AHRQ, the Joint Commission or the appropriate accrediting body to apply best practices, focusing on key operational areas that have the greatest impact on patient safety, quality and experience of care, including provider and staff competencies, standardized patient assessments for appropriateness of ASC utilization and risk of complications, a systems-based approach to medication management, and strict infection control monitoring.

Care Coordination

CMHC will establish a specific transfer policy that will govern the ASC's hospital transfers and admissions to ensure that such decisions are governed by the best care for the patient, which will include considerations regarding the complexity of service, subspecialty care, capacity of the receiving facility, geographic proximity, patient choice, and other relevant clinical factors. Similar policies and procedures exist today at CMHC's clinics and satellite locations including Topsham Family Medicine, Maine Urgent Care, and the Topsham Care Center. Hospital

transfers and admissions are a rare event for patients in an ASC. Nationally, the hospital transfer and admission rate for ASCs is 0.96 per 1,000 ASC admissions.

CONU Response to Post Technical Assistance Meeting Additional Information:

The applicant provided additional information which addressed the appropriateness of an ASC setting for surgery, governance structure, oversight and standards to ensure high quality care as well as care coordination between different care settings. Although this information is helpful, it does not change the fact that CMHC has a history of noncompliance with health and safety regulations (as outlined above). Furthermore, the applicant has no experience operating an ASC.

Of particular concern is that the proposed ASC is 20 miles from CMMC's Lewiston campus. This raises safety concerns. If an emergency arises during surgery where will the patient be transported for care? In addition, operating an ASC this far from its hospital raises logistical and staffing concerns. As acknowledged by the applicant, there is a shortage of trained specialists in §Gastroenterology, Breast Reconstruction/Surgical Oncology and Urology.

Deeming of Standard

As provided for at 22 M.R.S. § 335 (7)(A), if the applicant is a provider of health care services that are substantially similar to those services being reviewed and is licensed in the State, the requirements of this paragraph are deemed to have been met if the services previously provided in the State by the applicant are consistent with applicable licensing and certification standards.

CMHC does not operate and is not licensed as an Ambulatory Surgical Center provider, therefore the deeming standard does not apply.

Although CONU is concerned with the quality of care provided by CMHC in the past, CMHC is currently in compliance with all applicable licensing requirements in the current CON review standard. The Commissioner may use any information and source available to her under 22 MRS §338 to consider the quality of health care.

I. Conclusion

The CONU recommends that the Commissioner find that the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards.

III. Economic Feasibility

A. From Applicant

Deeming Standard

This section is subject to a deeming standard. The Certificate of Need Act provides:

> If the applicant is a provider of health care services that are substantially similar to those services being reviewed and is licensed in the State, the applicant is deemed to have fulfilled the requirements of this subparagraph if the services provided in the State by the applicant during the most recent 3-year period are of similar size and scope and are consistent with applicable licensing and certification standards.

22 M.R.S.A. § 335(7)(B)(2). CMHC has provided office-based physician services in the Topsham area for over a decade. The Topsham ASC will expand the range of services provided to include outpatient surgery in gastroenterology, orthopedics, cancer care, urology, and ear, nose and throat (ENT). CMHC has been a joint venture partner in its Auburn ASC for over two years and has experience providing outpatient surgical services such as orthopedics in an ASC setting. CMHC has decades of experience providing the full range of inpatient surgical services and substantially similar outpatient surgical services at CMMC's main campus in Lewiston. In addition, the physicians who will perform the surgical services at the Topsham ASC are highly experienced and currently perform such services in freestanding or hospital-based settings. CMMC and the Auburn ASC have provided outpatient surgical services consistent with all applicable licensing and certification standards. As a result of this collective experience, CMHC meets the deeming standard and is well-equipped to offer outpatient surgical services in Topsham.

A. Capacity of the Applicant to Support the Project Over Its Useful Life

CMHC plans to establish an ASC to add outpatient surgical services in the specialties it provides office-based services to enhance the continuity of care for its patients and improve local access to necessary outpatient surgical services in the lowest cost surgical setting. CMHC opened the 44,000-square-foot Topsham Care Center in 2018 and has a 20-year lease on the space, demonstrating CMHC's long-term commitment to the area. The multi-specialty Topsham ASC will provide surgical services in the specialties CMHC currently offers in Topsham: gastroenterology, urology, breast reconstruction, orthopedics and ENT.

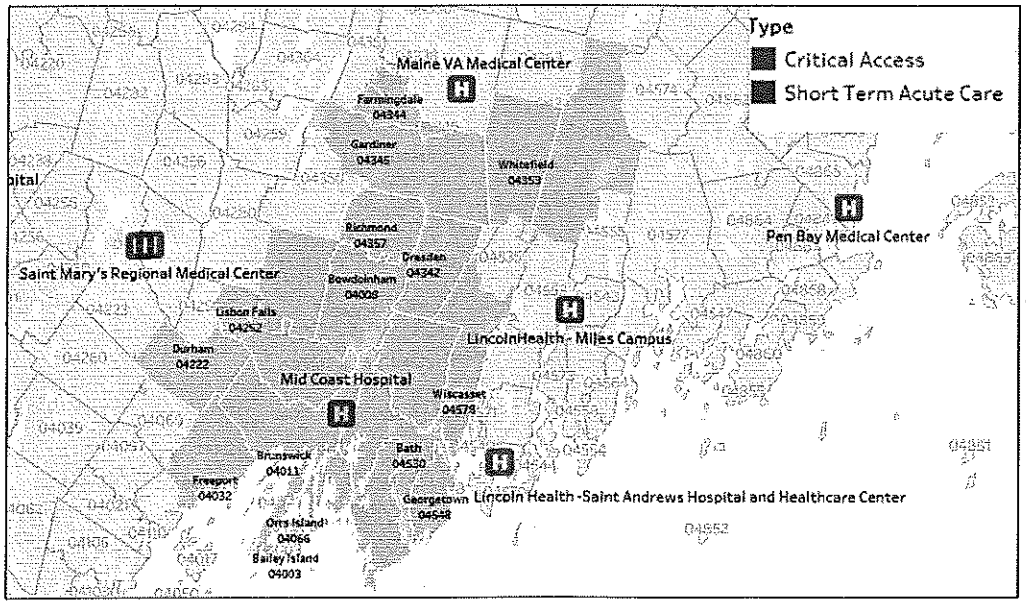
CMHC will partner with a developer to finance and construct the proposed Topsham ASC. The plan of finance for the project involves developer financing of the facility construction costs for two operating rooms and four procedure rooms and a long-term building lease

from the developer to CMHC. The plan of finance for the project also involves a long-term ground-lease from CMHC to the developer. These terms, accompanying operating and capital costs, projected volumes and the proposed rates have been incorporated into the financial pro forma for the proposed project. The cost of the ASC and its equipment subject to Certificate of Need review will be paid by CMHC with cash reserves.

B. Financial Assumptions Including Rates

The financial projections for the proposed project span the first three years of operation of the Topsham ASC beginning with its projected opening in fiscal year 2022 through fiscal year 2024. The assumptions underlying the financial projections appear below in Table 1 and involve: the addition of outpatient surgical services in the specialties currently offered by CMHC in Topsham; projected increases in utilization as a result of organic growth; and a modest increase in appropriate utilization as a result of a more cost-effective freestanding setting and decreased outmigration from the southern mid-coast region.[1]

The proposed ASC meets projected increased demand in the southern mid-coast region market from 2018 through 2023. The southern mid-coast region market is comprised of the 23 zip codes where the proposed Topsham ASC would be the closest facility offering the proposed services (the Southern Mid-Coast Region) (Figure 2). The projected rate of organic growth for outpatient surgery in the Southern Mid-Coast Region (excluding any procedures eligible to be performed in physician offices) for urology, orthopedics, gastroenterology, and ENT is estimated to be 12.3% for the period between 2018 – 2023 or 2.46% annually based on IBM Watson. The projected organic growth accounts for 3,247 cases per year, in addition to the current 26,339 cases, from 2018 through 2023. The national median for the number of outpatient surgical cases per operating room (OR) is 1,104[2], indicating that organic growth alone requires three additional ORs by 2023, assuming median levels of throughput (VMG Health, 2018). The



ASC

[1] IBM Watson is a leading national resource for healthcare utilization projections.

[2] VMG Health's 2018 Multi-Specialty ASC Benchmarking Study.

projected cases to be performed at the Topsham ASC and modeled for urology, orthopedics, gastroenterology, and ENT are expected to be 1,383 cases during the first year (2022) and 2,769 cases (84.2% of the total projected organic growth by 2023) for the second year (2023). The projected case volume at the proposed ASC in Year 3 represents increased demand for services in the catchment area from 2018 levels. The ASC's Year 3 volume assumptions are satisfied as a result of projected increased need in the market from utilization trends alone and do not require decreased outmigration or additional volume from proximate facilities.

For example, projected growth in outpatient orthopedic surgery is expected to be 15.3% or 842 cases in the same region for the period from 2018 – 2023 or 3.06% annually from the current 5,505 cases. The ASC is projected to have 300 new cases during the first year of operation (2022), and 301 new cases in the second year of operation (2023). Again, the projected increase in case volume as a result of organic growth in the service area alone according to IBM Watson satisfies the ASC's volume requirements. Surgical oncology and breast surgery cases are expected to originate from a 97-zip-code market representing CMHC's primary and secondary service areas due to the sustained shortage of existing specialists in those areas. Projected growth in outpatient surgical oncology and breast surgery is expected to double from 175 cases in the first year of operation (2022) to 351 cases in the second year of operation (2023).

CMHC has assumed modest annual growth in utilization based on the underlying utilization trend for outpatient surgeries which is increasingly directed to freestanding facilities at freestanding rates as projected by IBM Watson. The assumptions underlying the financial projection are presented in Table 1. The assumed average annual rate of growth for the services to be provided at the proposed ASC is projected to be 0.1022% per year in the financial module.

Table 1: Baseline ASC Projections.

Growth	FY2022	FY2023	FY2024
Volume Growth Overall	0.10%	0.10%	0.10%
Inflation Rates			
Salary and Wages	4.0%	4.0%	4.0%
Medical Supplies	3.0%	3.0%	3.0%
Drugs	5.0%	5.0%	5.0%
Supplies Other	3.0%	3.0%	3.0%
Source: Central Maine Healthcare			

Table 2 presents a summary of the financial projections for the Topsham ASC, inclusive of capital and lease costs. The financial projections evidence the financial feasibility of the project. The project is expected to have a positive contribution margin towards CMHC's overall operational, fixed and overhead costs. The projected lease and operating costs are financially sustainable based on projected modest rate increases and moderate volume growth reflective of IBM Watson projections in light of local demographics and a small shift in cases from a hospital-based setting to a freestanding setting due to a decrease in outmigration resulting from the more convenient setting with reduced driving time. Rates are assumed at freestanding facility rates based on the Medicare ASC Fee Schedule to reflect the lowest cost surgical setting. The overall government rate is assumed at a weighted average rate of $1,502 per case in Year 1.

Table 2: Financial Projections for Proposed ASC.

	FY2022	FY2023	FY2024
Net Patient Revenue	$ 3,440,741	$ 7,064,620	$ 7,273,646
Total Operating Expenses Before Interest/Depreciation	$ 2,561,210	$ 4,973,377	$ 5,136,378
Total Operating Expenses After Interest/Depreciation	$ 2,811,210	$ 5,488,377	$ 5,666,828
Contribution	$ 629,531	$ 1,576,244	$ 1,606,818
Source: Central Maine Healthcare			

Please see the CON Financial Module, and Exhibit B, CMHC's audited financials for 2018 and 2019. These exhibits further demonstrate CMHC's ability to support the project over its useful life.

C. Ability to Establish and Operate the Project in Accordance with Existing and Reasonably Anticipated Future Changes in Federal, State and Local Licensure and Other Applicable Rules

CMHC has successfully owned an ASC in Auburn with Spectrum Healthcare Partners. CMHC has had an ownership interest in this orthopedic ASC since 2018. During this time, CMHC has

collaborated to address changes in the ASC regulatory environment including the expansion of services that have been approved to be performed in an ASC setting, heightened rate pressure from payers, and the increased emphasis on care coordination as a result of patient expectations and bundled payments. This project, with its focus on continuity of care, relies on modest rate increases that reflect historical trends to be financially feasible. The projected ASC volumes in Year 3 do not require shifts in market share. Rather, the projected volumes reflect the growth in the need for outpatient surgical services. Any shifts in market share will be due to the ASC providing a high quality, more accessible, lower-cost option to receive the targeted services. Some of the services to be offered at the ASC will be new services for the region, affording greater convenience and lower geographic and transportation barriers to needed outpatient surgical services. CMHC has assumed a 2.0% increase in Medicare (FY 2023) and a 0.0% (FY 2023) increase in Medicaid payments, modest achievement of operational efficiencies, stable utilization of outpatient services, and stable levels of bad debt and charity care. Given these reasonable and conservative assumptions, the projected financial performance of the proposed ASC is financially feasible.

D. Existing and Future Regulations and Licensure

The 2020 COVID-19 pandemic has increased awareness about the critical role freestanding care settings can play in providing flexibility to the larger health care delivery system in its ability to treat patients safely and effectively. In March of 2020, CMS issued temporary new rules allowing hospitals to transfer patients to outside facilities such as ASCs and giving ASCs the ability to provide hospital services such as cancer procedures, trauma surgeries and other essential surgeries outside of the hospital setting. ASCs can enroll and bill as hospitals during the current emergency declaration as long as they comply with their state's Emergency Preparedness Plan (Services, 2020). The CMS "hospitals without walls" regulation acknowledges the importance of ASCs as a key asset to health systems and communities in their ability to respond to patient needs during national and state emergencies by providing a separate care setting in which patients unaffected by a pandemic or infectious disease can receive necessary care safely without coming into contact with infectious disease patients.

In addition, CMS finalized site neutral payments for the hospital outpatient prospective payment system in November 2018. The final rule created site-neutral reimbursement for outpatient services in hospital outpatient departments and physician offices that was phased in over two years (Centers for Medicare & Medicaid Services, 2018). This development is consistent with the overall movement towards site-neutral payments for outpatient surgical services. The Topsham ASC offers patients access to outpatient surgery services at the lowest cost setting generally available consistent with CMS's policy direction since at least 2015. Before the Topsham ASC would become operational in 2022, site neutral payments are expected to expand further. Moreover, commercial payers have begun implementing "site necessity" provisions for payment where payment is contingent on demonstration that no freestanding options are available for the service. This initiative began with imaging and is being expanded to include outpatient surgery. The development of the Topsham ASC is in response to and furtherance of these health care cost-cutting initiatives and offers a cost-effective, in-market option for patients and providers, increasing access to necessary and more affordable services.

B. CONU Discussion

i. CON Standards

Relevant standards for inclusion in this section are specific to the determination that the economic feasibility of the proposed services is demonstrated in terms of the:

- Capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project.
- The applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules. If the applicant is a provider of health care services that are substantially similar to those services being reviewed and is licensed in the State, the applicant is deemed to have fulfilled the requirements of this subparagraph if the services provided in the State by the applicant during the most recent 3-year period are of similar size and scope and are consistent with applicable licensing and certification standards.

ii. CONU Analysis

In order to assess the financial stability of CMHC, the CONU used financial ratios to measure profitability, liquidity, capital structure and asset efficiency. CONU looked at CMMC (CMHC's largest hospital) financial results to determine the economic feasibility of this transaction. Financial ratios were obtained from the Maine Health Data organization Hospital Financial Information Part 1 and Maine health Data Organization Hospital Financial Data Definitions available on MHDO's website http://mhdo.maine.gov/imhdo/. Additional information was obtained from the 2019 Almanac of Hospital Financial and Operating Indicators.

PROFITABILITY RATIOS

CONU used three profitability ratios to measure the applicant's ability to produce a profit (excess of revenue over expenses). Hospitals cannot be viable in the long term without an excess of revenues over expenditures. Cash flow would not be available to meet normal cash requirements needed to service debt and investment in fixed or current assets. Profitability has a large impact on most other ratios. For example, low profitability may adversely affect liquidity and sharply reduce the ability to pay off debt.

Operating margin: The operating margin is the most commonly used financial ratio to measure a hospital's financial performance. The operating margin measures the proportion of operating revenue retained as income and measures the hospital's profitability from providing patient care and other hospital operations.

This ratio is calculated as follows: ***Operating Income/Total Operating Revenue***

Operating Margin	2014	2015	2016	2017	2018
CMMC	1.76%	2.93%	(1.85%)	(3.26%)	(3.15%)
All Maine Hospital Median	(0.93%)	0.23%	(0.54%)	0.78%	0.39%
National Median	NAV	NAV	NAV	NAV	NAV

Performance implications: Increasing values are favorable

Net Operating Income (Loss): Net operating income is calculated by subtracting operating expense from operating revenue. This measure is used to look at how a hospital's net operating income performed in comparison with last years' figure and whether or not there is a positive or negative trend in the future.

Net Operating Income (Loss)	2014	2015	2016	2017	2018
CMMC	$5,794,015	$10,671,726	($7,027,065)	($12,323,834)	($11,796,794)
All Maine Hospital Median	($251,339)	$194,646	($341,747)	$533,127	$542,620
National Median	NAV	NAV	NAV	NAV	NAV

Return on Equity: This ratio defines the amount of excess revenue over expenses and losses earned per dollar of equity investment. Most not-for-profit hospitals received their initial, start-up equity capital from religious, educational, or governmental entities, and today some hospitals continue to receive funding from these sources. However, since the 1970s, these sources have provided a much smaller proportion of hospital funding, forcing not-for-profit hospitals to rely more on excess revenue over expenses and outside contributions. Many analysts consider the Return on Equity measure a primary indication of profitability. A hospital may not be able to obtain equity capital in the future if it fails to maintain a satisfactory value for this ratio. This ratio was calculated as follows: ***Excess of Revenue over Expenses/Fund Balance-Unrestricted***

Return on Equity	2014	2015	2016	2017	2018
CMMC	8.16%	13.61%	(11.91%)	(22.62%)	(31.59%)
All Maine Hospital Median	4.19%	2.06%	0.04%	7.56%	3.82%
National Median	7.30%	7.00%	5.80%	4.50%	NAV

Performance implications: Increasing values are favorable

Trends: Nationally many hospitals were showing improvements.

LIQUIDITY RATIOS

CONU used three liquidity ratios to measure the applicant's ability to meet short-term obligations and maintain cash position. A poor liquidity ratio would indicate that the hospital is unable to pay current obligations as the come due.

Current Ratio: Current ratio is a liquidity ratio that measures a company's ability to pay short-term obligations. The ratio is mainly used to determine if the hospital is able to pay back its short-term liabilities (debt and payables with its short-term assets (cash, inventory, receivables). From an evaluation standpoint, high values for the Current Ratio imply a high likelihood of being able to pay short term obligations. A ratio under 1 suggests that the hospital would be unable to pay off its obligations if they came due at that point.

This ratio is calculated as follows: ***Total Current Assets/Total Current Liabilities***

Current Ratio	2014	2015	2016	2017	2018
CMMC	0.99	1.12	0.86	0.75	0.81
All Maine Hospital Median	1.63	1.70	1.91	1.83	1.81
National Median	2.13	2.19	2.17	2.29	NAV

*Without Board Designated/Undesignated Investments

Performance implications: Increasing values are favorable

Trends: The Current Ratio continues to show improvements across many hospitals. This continued improvement implies that hospitals are generally well managing their liquidity.

Days Cash on Hand (Current): Days cash on hand is a common measure that gives a snapshot of how many days of operating expenses a hospital could pay with its current cash available. High values for this ratio usually imply a greater ability to meet short term obligations and are viewed favorably by creditors.

This ratio is calculated as follows: ***Cash & Investments + Current Assets Who's Use is Limited/ Total Advertising+ Salaries & Benefits + Other Operating Expenses + Interest/365 days***

Days Cash on Hand (Current)	2014	2015	2016	2017	2018
CMMC	25.2	31.6	18.1	11.4	24.0
All Maine Hospital Median	26.4	28.3	18.8	18.2	24.9
National Median	35.4	29.7	33.1	44.3	NAV

Performance implications: Increasing values are favorable

Average Payment Period: This ratio provides a measure of the average time that elapses before current liabilities are paid. Creditors regard high values for this ratio as an indication of potential liquidity problems.

This ratio is calculated as follows: ***Total Current Liabilities/Total Advertising + Salaries & Benefits + Other Operating Expenses + Interest/365***

Average Payment Period*	2014	2015	2016	2017	2018
CMMC	110.1	92.7	97.9	89.8	106.8
All Maine Hospital Median	76.5	75.5	71.5	57.9	54.9
National Median	54.9	54	52.6	53.7	NAV

*Current Liabilities

Performance implications: Decreasing values are favorable.

Trends: Nationally, this ratio has been creeping upwards during the last five years. Large hospitals have some of the higher values as do hospitals with low operating margins.

CAPITAL STRUCTURE RATIOS

CONU used three capital structure ratios in order to measure the applicant's capacity to pay for any debt. The hospital industry has radically increased its percentage of debt financing over the past two decades making this ratio vitally important to creditors who determine if a hospital is able to increase its debt financing. The amount of funding available to a hospital directly impacts its ability to grow.

Debt Service Coverage: This ratio measures the amount of cash flow available to meet annual interest and principal payments on debt. A DSCR of less than 1 would mean a negative cash flow. This ratio is calculated as follows: ***Excess of Revenue over Expenses + Depreciation + Interest/Interest + Previous Years Current LTD***

Debt Service Coverage	2014	2015	2016	2017	2018
CMMC	2.96	3.02	1.41	0.99	1.51
All Maine Hospital Median	2.79	2.99	2.09	2.90	2.69
National Median	2.67	3.39	3.33	2.32	NAV

Performance implications: Increasing values are favorable

Cash Flow to Total Debt: This coverage ratio compares a company's operating cash flow to its total debt. This ratio provides an indication of a hospitals ability to cover total debt with its yearly cash flow from operations. The retirement of debt principal is not a discretionary decision. It is a contractual obligation that has definite priority in the use of funds. Therefore, a decrease in the value of the Cash Flow to Total Debt ratio may indicate a future debt repayment problem. The higher the percentage ratio, the better the company's ability to carry its total debt.
This ratio is calculated as follows: ***Excess of Revenue over Expenses + Depreciation/Total Current Liabilities + Total Non- Current Liabilities***

Cash Flow to Total Debt	2014	2015	2016	2017	2018
CMMC	11.82%	14.81%	5.18%	3.98%	4.13%
All Maine Hospital Median	9.07%	10.70%	9.46%	14.44%	11.66%
National Median	23.50%	22.50%	19.80%	17.30%	NAV

Performance implications: Increasing values are favorable.

Fixed Asset Financing: This ratio defines the proportion of net fixed assets (gross fixed assets less accumulated depreciation) financed with long-term debt. This ratio is used by lenders to provide an index of the security of the loan. This ratio is calculated as follows: ***Long Term Debt/Net Plant, Property & Equipment***

Fixed Asset Financing	2014	2015	2016	2017	2018
CMMC	83.10%	83.55%	73.54%	75.89%	81.06%
All Maine Hospital Median	44.85%	43.67%	45.83%	47.31%	46.09%
National Median	55.50%	44.40%	45.20%	54.70%	NAV

Performance implications: Decreasing values are favorable.

Trends: Nationally, this ratio has declined for the last three years.

ASSET EFFICIENCY RATIOS

CONU used two asset efficiency ratios. These ratios measure the relationship between revenue and assets.

Total asset turnover ratio: Provides an index of the number of revenue dollars generated per dollar of asset investment. Higher values for this ratio imply greater generation of revenue from a limited resource base and are sometimes viewed as a positive indication of efficiency. This ratio is affected by the age of the plant being used by the hospital. This ratio is calculated as follows: ***Total Operating Revenue + Total non-operating Revenue/Total Unrestricted Assets***

Total Asset Turnover	2014	2015	2016	2017	2018
CMMC	1.20	1.37	1.39	1.55	1.47
All Maine Hospital Median	1.14	1.18	1.22	1.41	1.58
National Median	0.98	1.01	1.00	0.97	NAV

Performance Implications: Increasing values are favorable

Trends: Nationally, these values have held fairly steady for the last several years.

Fixed Asset Turnover Ratio: Measures the number of revenue dollars generated per dollar of fixed asset investment. High values for this ratio may imply good generation of revenue from a limited fixed asset base and are usually regarded as a positive indication of operating efficiency. This ratio is calculated as follows: ***Total Operating Revenue/Net Plant, Property, & Equipment***

Fixed Asset Turnover	2014	2015	2016	2017	2018
CMMC	2.27	2.67	2.56	2.82	2.82
All Maine Hospital Median	2.94	3.02	3.04	3.15	3.35
National Median	NAV	NAV	NAV	NAV	NAV

Performance implications: Increasing values are favorable

CONU Summary of Financial Ratios: Below is a chart summarizing the percentage of time CMMC Meets or exceeds Maine or National medians:

CENTRAL MAINE MEDICAL CENTER	RATIO	MAINE	NATIONAL
Profitability	Operating Margin	40%	NAV
Profitability	Net Operating Income	40%	NAV
Profitability	Return on Equity	40%	40%
Liquidity	Current Ratio	0%	0%
Liquidity	Days Cash on Hand	20%	20%
Liquidity	Avg. Payment Period	0%	0%
Capital Structure	Debt Service Coverage	40%	20%
Capital Structure	Cash Flow to Total Debt	40%	0%
Capital Structure	Fixed Asset Financing	0%	0%
Asset Efficiency	Total Asset Turnover	80%	80%
Asset Efficiency	Fixed Asset Turnover	0%	NAV

NAV-Not available

CMMC meets or exceeds Maine performance averages in 1 out of 11 measures and exceeds National Averages in 1 out of 8 measures.

CONU expanded this analysis to compare the 2018 and 2019 operations. The chart below shows that CMMC performed worse in three measures of profitability, two measures of liquidity, two measures of capital structure and one measure of asset efficiency between 2018 and 2019.

CMMC		2018	2019	Performance
Profitability	Operating Margin	(3.15%)	(4.83%)	Worse
Profitability	Net Operating Income	($11,796,794)	($19,425,758)	Worse
Profitability	Return on Equity	(31.59%)	(111.30%)	Worse
Liquidity	Current Ratio	0.81	0.76	Worse
Liquidity	Days Cash on Hand	24	58.4	Better
Liquidity	Avg. Payment Period	106.8	151.7	Worse
Capital Structure	Debt Service Coverage	1.51	0.72	Worse
Capital Structure	Cash Flow to Total Debt	4.13%	0.62%	Worse
Capital Structure	Fixed Asset Financing	81.06%	80.78%	Better
Asset Efficiency	Total Asset Turnover	1.47	1.29	Worse
Asset Efficiency	Fixed Asset Turnover	2.82	3.03	Better

The applicant addressed this section by submitting their Certificate of Need financial module and Central Maine Healthcare Corporation and Subsidiaries Fiscal Year Ending June 30, 2019 and 2018 audited financial statements prepared by BKD, LLP. Supplemental information requested by CONU has also been included in the record. CONU evaluated the information supplied by the applicant to determine if the assumptions underlying its financial projections are reasonable and demonstrate an ability to support the project financially over its useful life. Below is the projected income statement for the proposed Topsham ASC first three full years of operation provided as part of the CON financial module (adjusted by CONU to include depreciation expense in totals).

Table A:

Topsham ASC (Projected) in (000's)	Year 1	Year 2	Year 3
Outpatient Care Revenues	7062	7270	7484
Inpatient Care Revenues	0	0	0
Gross Patient Care Revenues	**7062**	**7270**	**7484**
Free Care	0	0	0
Provision for Bad Debt	0	0	0
Contractual Adjustments	0	0	0
Net Patient Care Revenue	7062	7270	7484
Operating Expense			
Salaries	1158	1204	1252
Benefits	255	265	275
Supplies	1262	1314	1368
Other Expense	2813	2884	2969

Depreciation	500	500	500
Interest	0	0	0
Total Operating Expense	5988	6167	6364
Net Operating Income (Loss	1074	1103	1120

CONU asked for more detail surrounding case volume and rates charged to support assumptions regarding revenue projections. In response the applicant submitted the following table:

Table B:

	Year 1			Year 2			Year 3		
	Projected Cases	Projected	Annual	Projected Cases	Projected	Annual	Projected Cases	Projected	Annual
Service	Volume	Charge	Revenue	Volume	Charge	Revenue	Volume	Charge	Revenue
Gastroenterology	851	$1,256	$1,068,856	1703	$1,288	$2,193,464	1705	$1,325	$2,259,125
Orthopedics	300	$2,007	$602,100	601	$2,059	$1,237,459	602	$2,117	$1,274,434
Breast Reconstruction	175	$3,107	$543,725	351	$3,186	$1,118,286	351	$3,277	$1,150,227
Urology	169	$3,045	$514,605	339	$3,123	$1,058,697	339	$3,212	$1,088,868
Ear, Nose andThroat	45	$3,727	$167,715	89	$3,822	$340,158	89	$3,931	$349,859
Other (Describe)	0	$0	$0	0	$0	$0	0	$0	$0
Other (Describe)	0	$0	$0	0	$0	$0	0	$0	$0
Other (Describe)	0	$0	$0	0	$0	$0	0	$0	$0
Other (Describe)	0	$0	$0	0	$0	$0	0	$0	$0
Other (Describe)	0	$0	$0	0	$0	$0	0	$0	$0
Total	1540	$13,142	$2,897,001	3083	$13,478	$5,948,064	3086	$13,862	$6,122,513

CONU notes that Year 1 of Table B is a partial year and Year 2 and Year 3 are the first full years of operation. CONU cannot reconcile the volume and revenue projections in Table B with the first two years of operation from Table A (financial module). Table A reports projected revenues of $7,062,000 and $7,270,000 while Table B reports projected revenues of $5,984,064 and $6,122,513. The applicant utilized a growth rate of .10% to predict increases in annual patient volume. The applicant further assumes an organic growth rate of 12.3% over the next five years for surgical services and procedures that would be provided by the proposed ASC. Assumptions regarding population growth and the projected need for services in the service area will be further discussed in the Public Need section of this preliminary analysis.

CONU asked the applicant to provide a detailed staffing plan for the Topsham ASC which is included below:

Staff:
Director (1 FTE)
Patient Service Representative (1 FTE)
Patient Service Supervisor (1 FTE)
Environmental Services (1 FTE)
Security (1 FTE)
Registered Nurses (6.45 FTE)
Technician (2.9 FTE)

Surgeons: *
ENT (1)
Orthopedics (1)
Gastroenterology (3)
Breast Reconstruction/Surgical Oncology (3)
Urology (1)

*Surgeons will be cross utilized with other sites in the CMHC system.

A 4% annual growth rate in Salaries and benefit expense is projected for the first three years of operation. Medical supplies, Drugs and Other supplies expense are projected to grow at 3%, 5% and 3% annually for the first three years of the project.

CONU asked for additional information regarding the utilization of operating and procedure rooms and received the following response:

CMH is planning to operate the Topsham ASC 40 hours per week from 8 a.m. to 5 p.m., Monday through Friday. CMH will operate the proposed ASC five days per week, eight hours per day, creating 2,000 available hours per operating room (or a total of 4,000 available hours) a year performing surgery from 8:00 a.m. to 5:00 p.m., closing for an hour during lunch. Utilizing two operating rooms, CMH will operate at 47.7% capacity in Year 1, and 95.6% and 95.7% capacity in Years 2 and 3 respectively. The average case time is estimated at 133 minutes per surgery."

"CMH will operate two procedure room, five days per week, eight hours per day, creating 2,000 available hours per procedure room (or a total of 4,000 available hours) a year performing procedures from 8:00 a.m. to 5:00 p.m., closing for an hour during lunch. Utilizing two procedure rooms and leaving two spaces as shell space for future expansion, CMH will operate at 42.1% capacity in Year 1, and 84.3% and 84.4% in Years 2 and 3 respectively. The average case time is estimated at 95 minutes per procedure."

"CMH applied an efficiency factor of 80% (DHHS guidelines) to accommodate for unused time in the day."

"The table below demonstrates the overall projected utilization of the operating and procedure rooms"

		Year 1	Year 2	Year 3
Surgical Volume		689	1380	1381
Total Time Needed		91664	183516	183703
Total Hours Needed		1528	3059	3062
Efficiency Factor	80%	1910	3823	3827
Operational Capacity		47.70%	95.60%	95.70%
Procedure Volume		851	1703	1705
Total Time Needed		80832	161830	161996
Total Hours Needed		1347	2697	2700
Efficiency Factor	80%	1684	3371	3375
Operational Capacity		42.10%	84.30%	84.40%

The applicant states that the Topsham ASC would be 95.7% utilized by 2023 and that the projected volume is only a small fraction of the 12.3% projected growth in surgical cases in the area and therefore would not have a detrimental effect on Mid Coast – Parkview Health. CONU was not provided with detailed information about the current capacity of Mid Coast – Parkview Health, however, based on directly affected party comments in a Mid Coast – Parkview Health letter dated August 21, 2020 the directly affected party states that "Mid Coast – Parkview Health has an ASU, which runs in a fashion very similar to a freestanding ASC" and "Mid-Coast – Parkview Health currently offers the same surgical and procedural services that would be offered at the Topsham ASC." The August 21, 2020 letter further described the overall ambulatory surgery unit utilization at Mid Coast Parkview Health being under 50% from 2017 through 2019 indicating the potential capacity to absorb increased volume in the area. The applicant did not conduct a capacity analysis between Mid Coast -Parkview Health's ASU and their proposed ASC. This analysis would have determined if there was a gap in surgical capacity in the health service area.

Site-neutral payments:
The Centers for Medicare & Medicaid Services (CMS) is encouraging site-neutral payments between sites of services and further proposes changes that would make healthcare prices more transparent for patients so that they can be more informed about out-of-pocket costs. The applicant asserts that the predicted volumes will be achieved because ASC's can offer a lower cost service to patients than a hospital system. CONU is concerned that should site-neutral payments become fully implemented the competitive advantage of providing a low-cost alternative to hospital services will vanish. Projected volumes and rates may be insufficient to support the project financially over its useful life.

Impact of COVID 19:
The headline in a June 14, 2020 Portland Press Herald article states "Pandemic takes staggering financial toll on Maine hospitals". The article states that Maine hospitals began losing about $250,000,000 per month after suspending elective and preventative care according to Steven Michaud, president of the Maine Hospital Association. Initially patient volume fell by half and is only recently beginning to make a comeback. Provider Relief funds within the CARE Act may

mitigate some of the financial damage but cash flow will continue to be a problem. Hospitals have had to take measures to address the revenue gap. CMMC initiated a furlough of 10% of its staff in April and has recently had to adjust its budget at its recently approved cancer center to account for rising construction costs. As shown above CMMC's financial performance worsened during 2019 before the COVID 19 pandemic hit. The results of future operations will undoubtedly be worse leaving its' ability to fund the proposed Topsham ASC uncertain if the results of operations do not meet expectations. Maine's unemployment and labor force participation rate declined significantly during the early days of the pandemic and is only now recovering. The delay of elective medical procedures will result in worse health outcomes and more expensive care.

Directly Affected Party Comment:

CMHC has been beset with losses in recent years, and it is not at all clear that the organization possesses the financial wherewithal to get such an endeavor off the ground, particularly if it fails to meet initial projections. An indeed: what are those projections? The application makes varied and conflicting claims as to the income such a facility would generate and what it would cost to run it.

Post Technical Assistance Meeting Additional Information – Economic Feasibility

Developer Financing Enhances CMHC's Ability to Support the Project

CMHC plans to utilize developer financing which will allow it to reduce its initial capital investment for the construction of the Project and focus its financial investment on the aspects of the Project where it is uniquely positioned to add value. CMHC will utilize a third-party developer for the real estate aspects of the Project including the land acquisition and construction of the proposed ASC. In this common strategic financing model, the developer pays for the land and construction of the ASC facility and CMHC pays rent in a long-term lease arrangement. This structure reduces CMHC's upfront cash investment in the Project to approximately $4M, a readily manageable amount for an organization with over $500 million of annual revenues. CMHC's financial modeling indicates that its $4M initial cash investment will be fully repaid from revenue generated by the ASC's operations in Year 3. The cash flow generated from ASC operations will be applied, in part, to the lease payments. CMHC's capital will primarily be used for the patient-focused operations, staff and technologies that ensure the highest quality care and experience for ASC patients.

Financial Performance

CMHC continues to make progress in its multi-year system turnaround and, prior to the COVID-19 pandemic, was experiencing sustained growth with 15 months of positive EBIDTA margins. Despite the COVID-19 pandemic, CMHC has demonstrated improvement in key financial metrics even subsequent to the filing of its application. A copy of CMHC's FY2020 audited financials are attached as Appendix B. Below are additional updated metrics of financial strength from CMHC's recently completed FY2020 audited financials for comparison.

	FY2019	FY2020
Days Cash on Hand	52	92

EBITDA Margin	2.2%	3.3%

While every indication is that the Project will be accretive to CMHC's bottom line, any future support of the Project that is required by CMHC is well-within CMHC's current financial capacity even without the expected, improved financial capacity resulting from the end of the pandemic and CMHC's continued financial improvements. MaineHealth's arguments to the contrary are simply specious and this effort to twist the fact that this Project will be financially self-supporting into an inability of CMHC to financially support the Project is unfair and misguided. The reality is that CMHC carefully and strategically plans projects, including the ASC Project, to grow and strengthen the system by offering its patients high quality services at the right price and in the right place. The reality is also that CMHC has the existing financial capacity to support this Project.

CONU Response to Post Technical Assistance Meeting Additional Information:

The applicant's additional information regarding the advantages of developer financing is useful. However, as outlined above, CONU is concerned with several areas that still may need more information from the applicant.

1) There is a lack of analysis of surgical capacity in the Mid Coast area. Mid Coast -Parkview hospital is showing a 50% or lower utilization rate for their outpatient surgical operations. Without fully analyzing the Mid Coast areas market capacity it is not possible to adequately assess the demand for additional services in the area.

2) CONU is concerned about the impact of site-neutral payments on the projects bottom line. The competitive advantage of being a low-cost provider could be compromised if site neutral payments are implemented.

3) The applicant states that its' financial position has improved in 2020. An examination of the 2020 financial statements submitted by the provider shows that Central Maine Healthcare continued to experience operating losses in 2020. Poor financial performance has been a long-term trend as shown in the above CON analysis.

4) Discrepancies and confusion around financial projections provided by the applicant.

5) The impact of the COVID-19 pandemic has not fully been realized by the end of the time period included in the 2020 financial statements. Note 20 of the Notes to Consolidated Financial Statements reads in part:

"The extent of the COVID-19 pandemic's adverse impact on the Corporation's operating results and financial condition has been and will continue to be driven by many factors, most of which are beyond the Corporation's control and ability to forecast. Such factors include, but are not limited to, the scope and duration of stay-at-home practices and business closures and restrictions, government-imposed or recommended suspensions of elective procedures, continued declines in patient volumes for an indeterminable length of time, increases in the number of uninsured and underinsured patients as a result of higher sustained rates of unemployment,

incremental expenses required for supplies and personal protective equipment, and changes in professional and general liability exposure."

"Because of these and other uncertainties, the Corporation cannot estimate the length or severity of the impact of the pandemic on the Corporation's business. Decreases in cash flows and results of operations may have an impact on debt covenant compliance and on the inputs and assumptions used in significant accounting estimates, including estimated implicit price concessions related to uninsured patient accounts and potential impairments of long-lived assets." – Note 20 from *CMHC Audited Financial Statements for 2020.*

Deeming of Standard

As provided for at 22 M.R.S §335 (7)(B)(2), if the applicant is a provider of health care services that are substantially similar to those services being reviewed and is licensed in the Stare, the applicant is deemed to have fulfilled the requirements of this standard if the services provided in the State by the applicant during the most recent 3-year period are of similar size and scope and are consistent with the applicable licensing and certification standards.

The applicant has not operated and is not licensed to operate an ASC; therefore, the deeming standard does not apply.

iii. Conclusion

CONU RECOMMENDATION: CONU recommends that the Commissioner determine that the applicant has **NOT** met their burden to demonstrate: (1) the capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project; and (2) the applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules.

IV. Public Need

A. From Applicant

A. The Project Will Substantially Address Specific Health Problems as Measured by Health Needs in the Area

A new ASC in the Topsham community will address a recognized state and CMHC system health need to increase access to care by expanding the availability of multispecialty surgical services in the local community and providing such services in a cost-effective setting. The expanded access to care offered by the Topsham ASC is an important element of CMHC's system wide strategy to enhance local options for addressing the significant health problem of cancer. (2019 Maine Shared Community Health Needs Assessment). Sagadahoc County, the primary location for the Southern Mid-Coast Region, has a high incidence rate of breast cancer and a high mortality rate for prostate cancer (Table 3). The specific specialties of surgical oncology and urology that will be offered at the Topsham ASC will help the community combat cancer by creating greater local access to specialists, including surgical oncologists. The specific health needs of the area are currently being serviced outside of the area resulting in significant outmigration for care. As the population continues to age, local patients' ability to seek care outside of the community is likely to decline, creating even greater public need for care that is available in the local area.

Table 3: Cancer Rates. *Source: The Maine 2018 Annual Report of Cancer, Maine CDC Cancer Registry.*

	Sagadahoc County	Maine State Average
Breast Cancer Incidence per 100,000 Population	131.5	126.6
Prostate Cancer Mortality per 100,000 Population	34.5	19.6

The Topsham ASC will also improve access to other necessary outpatient surgical care and stem the considerable outmigration of outpatient multispecialty surgical services from the Southern Mid-Coast Region (Table 4). For example, of 2,391 gastroenterology patients in 2018, 778 (33%) sought care outside of the service area and 56 (2.3%) patients received care in an ASC setting. Of 1,497 orthopedic patients in 2018, 744 (49.7%) went outside of the service area for care and only 24 patients or 1.6% received care in an ASC setting. Of 1,187 ENT patients in 2018, 1,497 (67.1%) received care outside of the service area. Of 1,497 urology patients, the percentage that received care outside of the service area was slightly lower at 1,345 (33.7%). Looking at colorectal procedures, for which patients prefer to stay as close to home as possible, 50% of patients currently travel outside the service area to receive

treatment (Maine Health Data Organization, 2020). These numbers evidence that a significant number of patients travel outside of the service area to obtain surgical care services that could be accessed locally at the Topsham ASC.

Table 4: Outmigration Analysis. *Source: Maine Health Data Organization, and CMHC All Payor Data.*

		2018 Percentage	2018 Cases
Gastroenterology	Existing ASCs	2%	56
	In Area	65%	1,557
	Out of Area (excluding ASCs)	33%	778
	Total	**100%**	**2,391**
Orthopedics	Existing ASCs	2%	24
	In Area	49%	729
	Out of Area (excluding ASCs)	50%	744
	Total	**100%**	**1,497**
ENT	Existing ASCs	0%	1
	In Area	33%	389
	Out of Area (excluding ASCs)	67%	797
	Total	**100%**	**1,187**
Urology	Existing ASCs	0%	-
	In Area	66%	892
	Out of Area (excluding ASCs)	34%	453
	Total	**100%**	**1,345**

Consumers of health care benefit when economic barriers to care are reduced by the availability of more affordable options. Studies have shown that in this era of high-deductible health plans, without access to convenient low-cost care, patients will forgo care (Riley, 2018). High deductibles and the high cost of care continue to be a significant challenge for Mainers even after Maine's recent Medicaid expansion. Maine had the highest single-person deductible for employer coverage in the country in 2018 (Collins, Radley, & Baumgartner, 2019). As high deductible health plans have proliferated, the number of underinsured patients in Maine has increased. Deductibles are rising faster than workers' wages, which can cause consumers to face greater exposure to high health care costs. Employers are covering a smaller percentage of deductibles through employer health savings accounts or health reimbursement account contributions, leaving many individuals responsible for a larger percentage of the deductible. For many, especially individuals in families with modest resources, this financial burden is too high a price to bear and can leave them seriously underinsured. Figure 3 depicts the growing financial burden faced by workers and Figure 4 depicts the growing percentage of workers with high deductible health plans.

Figure 3: Premiums and Deductibles Rising. *Source: Kaiser Family Foundation.*

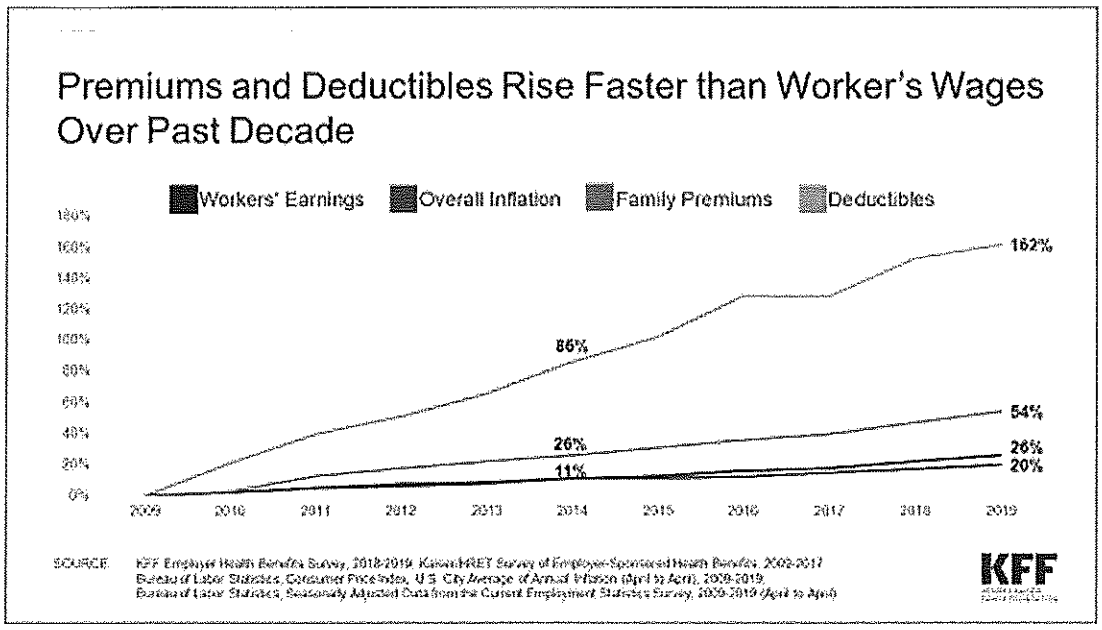
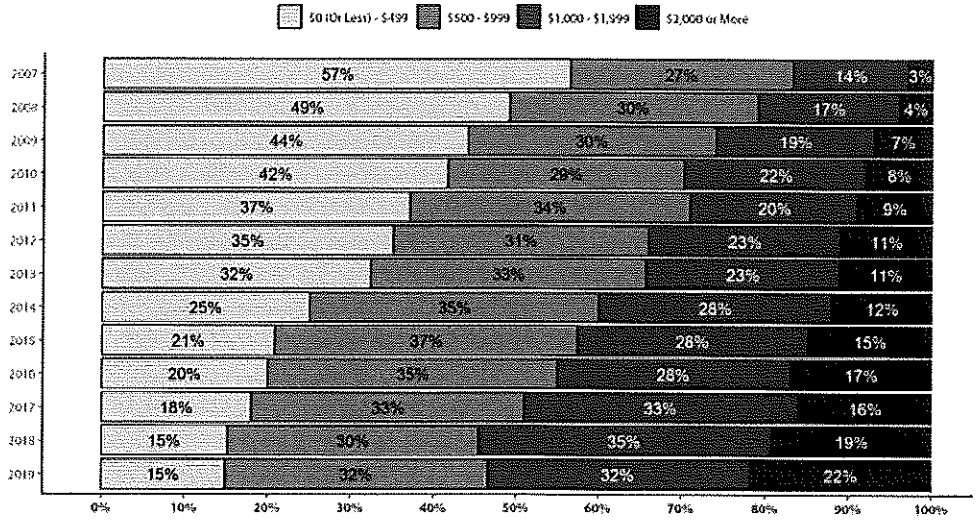


Figure 4: Distribution of General Annual Deductibles for Single Coverage. *Source: Kaiser Family Foundation.*

Figure 7.18
Among Covered Workers with a General Annual Deductible, Distribution of General Annual Deductibles for Single Coverage, Reduced by Any HRA/HSA Contributions, 2007-2019



Tests found no statistical difference from distribution for the previous year shown ($p < .05$).
NOTE: Account contributions include an employer's contribution to an HSA or HRA. These estimates include workers enrolled in HDHP/SOs and other plan types. Average general annual deductibles are for in-network providers.
SOURCE: KFF Employer Health Benefits Survey, 2018-2019; Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2007-2017

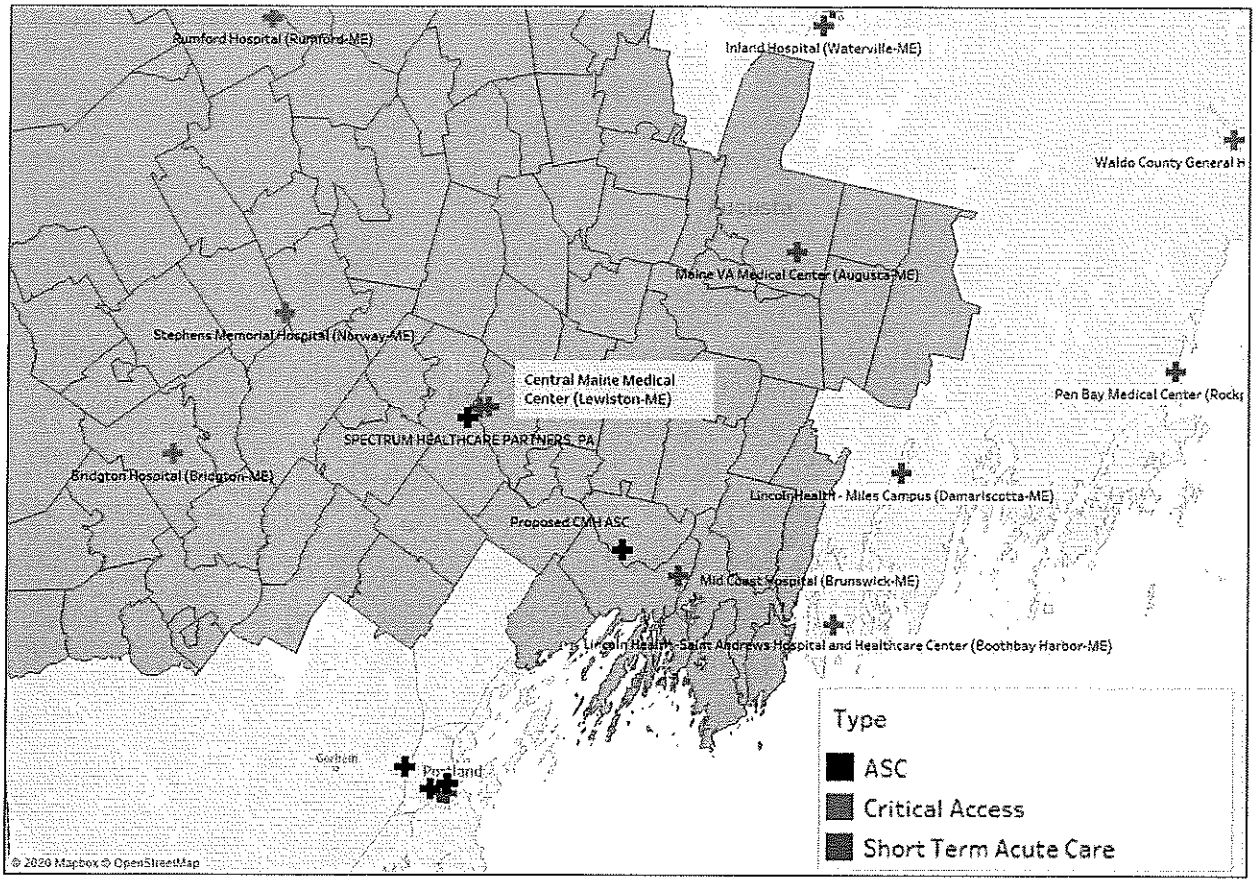
As a result of the rapid growth in high deductible plans, health care consumers, including Maine consumers, are increasingly price sensitive which makes the ASC setting a valuable alternative for patients. In June of 2019, President Trump signed an executive order "requiring hospitals and insurance companies to disclose negotiated rates for health care services and inform patients of their financial responsibility prior to a surgical procedure." (Stewart, 2019) This executive order is intended to provide greater price transparency as more patients shop for care. The State of Maine has also embraced the trend towards greater price transparency. In 2019, Governor Mills signed four bills related to this issue, specifically:

- A measure to establish a prescription drug importation program;
- A drug transparency law that requires brand-name pharmaceutical manufacturers to report price increases of more than 20% for medications costing over $10;
- A bill to create a Prescription Drug Affordability Board; and
- A measure requiring pharmacy benefit managers to reveal rebates they receive from drug makers (Bunis, 2019).

The proposed ASC addresses the affordability challenge by offering outpatient surgical services at freestanding rates—generally the lowest-cost care setting. See Table 8 for a comparison of patient out-of-pocket costs in ASCs as compared to hospital outpatient department (HOPD) settings. This project will provide care that will be on average 47% less expensive for patients than comparable care in the Southern Mid-Coast Region. The project aims to reduce the likelihood that patients will avoid medically necessary care because of the barrier of cost.

Over the last three decades, the utilization of lower cost outpatient care settings has increased dramatically across the United States and in Maine. At the same time, the utilization of expensive inpatient care settings has decreased significantly. ASCs are generally the lowest cost care setting compared to both inpatient and most hospital-based outpatient offerings. Nationally, there are thousands of ASCs providing safe, cost-effective care. ASCs are expected to continue to experience increased utilization because of the national and State of Maine trends towards low cost care settings.

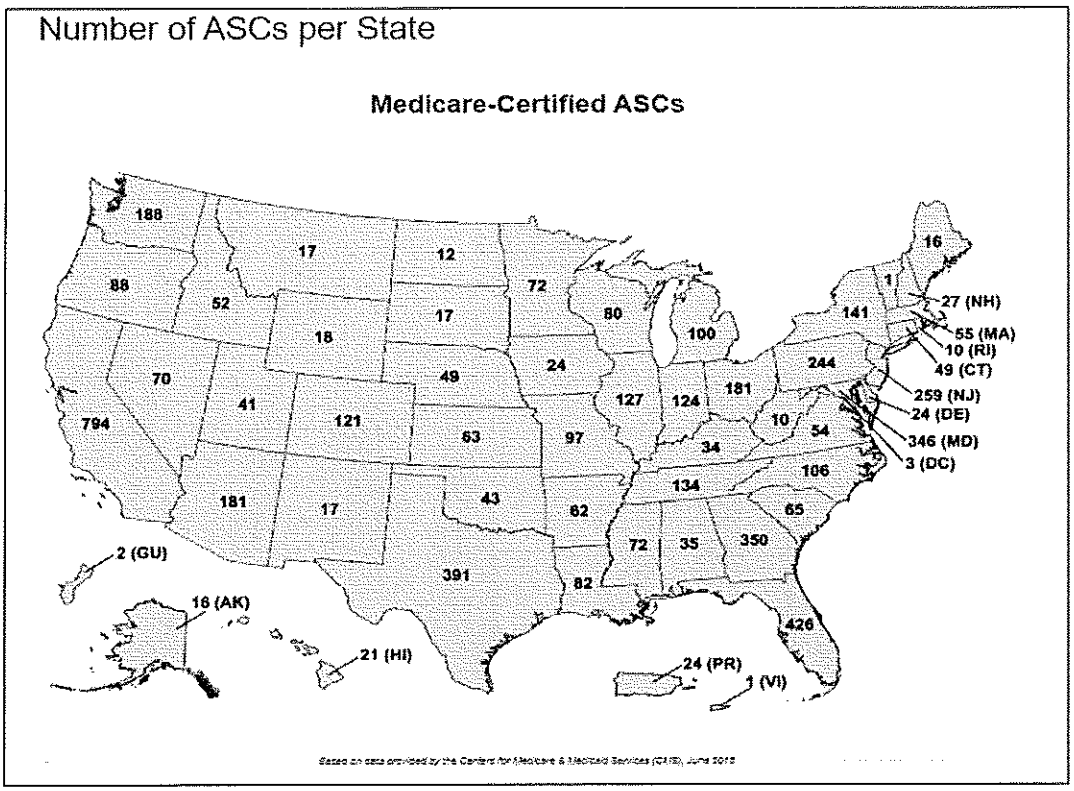
Figure 5: Map of ASCs with Similar Specialties in Area Surrounding CMHC. *Source: IBM Watson.*



There are 16 ASCs licensed and operating in Maine, only six of which specialize in services other than ophthalmology, plastics or dental[3]. *See* Figure 5. Maine has fewer ASCs than all but a few states and fewer ASCs on a per capita basis than every state but Vermont, Rhode Island and West Virginia. *See* Figure 6. The Southern Mid-Coast Region currently does not have an ASC option. This project would fill an important gap in the health care delivery system by bringing a missing care setting to the Southern Mid-Coast Region--an ASC that is able to deliver high quality care in a low-cost setting. See Exhibit C, Letters of Support.

[3] Figure 5 shows the location of five of the six ASCs that specialize in services other than ophthalmology, plastics or dental; four are in the Portland area and one is in Auburn. The ASC in Bangor is not shown on Figure 5.

Figure 6: Number of ASCs per State in the United States. *Source: Ambulatory Surgery Center Association, 2020.*

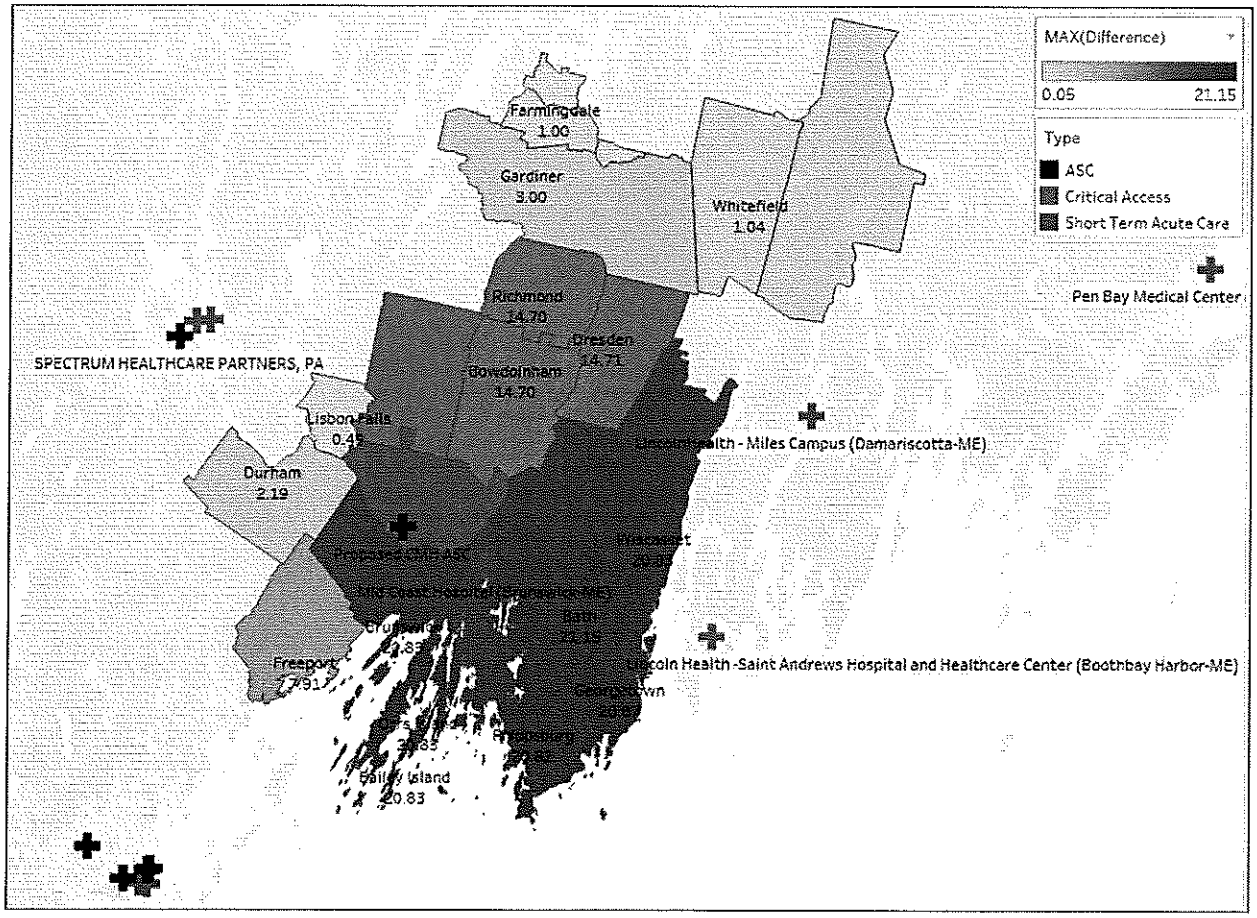


B. Positive Impact on Health Status Indicators

By increasing access to a closer, low cost health care facility that delivers high quality care, the Topsham ASC can improve health status outcomes in the community (Centers for Medicare & Medicaid Services, 2017). For the individuals in the Southern Mid-Coast Region, the future Topsham ASC would be the closest, lowest-cost care setting for the proposed services. The addition of this low-cost setting will improve geographic access to care, which has been shown to improve health status indicators. As referenced above, Sagadahoc County has a breast cancer incidence rate of 131.5 per 100,000 people compared to the Maine state average of 126.6 per 100,000 people. An ASC in Sagadahoc County would allow local access to screenings and breast reconstruction surgery at a lower cost which is likely to have a positive impact on health status indicators. A local option can also reduce health care burdens such as travel time, particularly travel time associated with multiple follow-up visits, which can also have a positive impact on health status indicators. The Southern Mid-Coast Region has a population of 107,790 individuals which is expected to grow to 108,423 individuals by 2023 (IBM Watson, 2020).

Without the future Topsham ASC, patients in the Southern Mid-Coast Region would have to travel an average of 24.6 minutes further round-trip for lower-cost health care. For nine of the 23 zip codes comprised of over 47,061 individuals or 42.5% of the total population in the Southern Mid-Coast Region, the added travel would be an average of 41.7 minutes further round trip for lower cost health care (IBM Watson, 2020). Over 21% of individuals in the Southern Mid-Coast Region are over age 65, and this number is projected to grow to over 23% by 2023 (IBM Watson, 2020). For the elderly population, time, access, and cost can have a disproportionately negative effect on the overall quality of the health care they receive. Providing patients in the Southern Mid-Coast Region with a closer, low cost, high quality health care option at the Topsham ASC will ease time constraints and the economic burdens of travel and cost of care associated with the surgical procedure, as well as the often-numerous follow-up office visits after the surgical procedure.

Figure 7: Difference in Minutes for Each Zip Code between Proposed Topsham ASC and Next Closest ASC. *Source: IBM Truven.*



C. Accessibility by All Residents of the Proposed Service Area

The Topsham ASC will increase access by all residents in the service area by providing an affordable, local, outpatient surgical care setting. In September of 2019, Definitive Healthcare released a survey of outpatient trends for 2020. The survey indicated that the increasing rise of consumerism and increases in ASC reimbursement ranked as the third and fourth most relevant factors driving outpatient growth in 2020 (Definitive Healthcare, 2019). A separate study examined the commercial insurance cost savings in ASCs (Advancing Surgical Care, 2016). This study also-documented that ASCs are priced at 53% of HOPD Medicare rates. A study conducted by the Healthcare Bluebook and HealthSmart has examined savings beyond differences in Medicare rates. It was estimated that ASCs save patients and employers an estimated $38 billion per year, even though 48% of ASC eligible procedures were performed in higher-cost HOPD settings. Of this $38 billion in cost savings, $5 billion is shared by patients through lower deductibles and coinsurance payments (Advancing Surgical Care, 2016).

CMHC is committed to providing access to high quality, low cost, medically necessary health care to all patients. Table 5 below depicts the financial assistance offered to patients at CMMC, Bridgton Hospital, and Rumford Hospital. CMHC also plans to offer financial assistance to patients at the Topsham ASC. As evidenced in Table 6, CMHC's commitment to the communities in which it serves is anticipated to result in a greater percentage of Medicare and Medicaid patients and a lower percentage of commercial patients than the national median for ASCs. CMHC has included the percentages in Table 6 in its financial projections to coincide with the general payor mix in CMHC's service area and the local region.

Table 5: Financial Assistance. *Source: Central Maine Healthcare.*

Size of family unit	**Maine Financial Assistance*	**CMMC, BH, RH Financial Assistance*
1	$18,735	$24,980
2	$25,365	$33,820
3	$31,995	$42,660
4	$38,625	$51,500
5	$45,255	$60,340
6	$51,885	$69,180
7	$58,515	$78,020
8	$65,145	$86,860
For each additional person, add this amount.	$6,630	$8,840

Last Updated: February 18, 2019

Table 6: Payor Mix as a Percentage of Cases. *Source: Intellimarker – VMG*

Payor	Future Topsham CMHC ASC (FY 2022)	National Median for ASC	Projected Maine State Insurance Coverage Estimates (FY 2022)
Medicare	42.20%	33.00%	23.60%
Medicaid	9.80%	7.00%	17.40%
Commercial	40.90%	47.00%	54.60%
All Other	7.20%	12.00%	4.30%

There are a significant number of cases in the Southern Mid-Coast Region that could be performed in a lower-cost setting, easing the economic burden for many patients in the region and increasing access to affordable care. Looking specifically at outpatient estimates and projections provided by IBM Watson in the services of orthopedics, gastroenterology, ENT, and urology, within the 23 zip codes, there are an estimated 49,740 cases (including those performed in physician offices) that can be performed in an ASC. This is expected to grow by 9.7% or 4,821 cases to 54,562 by 2023 (IBM Watson, 2020). The number of outpatient procedures eligible to be performed in an ASC is growing each year in these specific specialties. Considering surgical oncology and breast health services that could be performed in an ASC, there are 524.5 cases in the 23 zip codes with a projected increase to 534.6 cases in 2023 (IBM Watson, 2020).

D. Demonstrable Improvements in Quality and Outcome Measures

Perhaps most importantly, and as highlighted by the recent pandemic, the Topsham ASC offers a care setting that provides very high-quality health care that keeps patients safe. Based on a study conducted by the California Ambulatory Surgery Association, ASCs have an infection rate that is six times lower than hospitals (Beckers ASC Review, 2017). This rate is based on the quality indicators shown in Table 7.

Table 7: Quality Indicators of ASCs. *Source: Centers for Medicare & Medicaid Services, 2017.*

Quality Indicators	Adverse Risk Effects
Hospital Transfer/Admission	Return to Surgery for reasons other than bleeding
Post-Operative Wound Infections (Within 30 days of the procedure or 90 days if the procedure involved an implant of any kind)	Excessive Bleeding requiring return to the Operating Room or transfer
Patient Burn	Cardiac or Respiratory Arrest
Patient Fall in the ASC	Medical Device Errors
Medication Error	Wrong Site Surgery
ER Visit within 48 hours of Discharge	Unintentional retained foreign body

ASCs are also more efficient than hospitals with respect to outpatient procedures, with the same procedures taking 25 percent less time. The efficiencies are largely due to an ASC's limited scope of procedures and specialized nursing and support staff. Without the interruption of emergency cases, turnaround time for operating rooms is significantly lower. The Topsham ASC will develop protocols for implementing quality initiatives in accordance with national benchmarks. CMHC plans to work with physician providers at the Topsham ASC who have substantial experience using quality initiative scorecards and plans to have the Topsham ASC management utilize these scorecards with the goal of surpassing national best-practices.

B. CONU Discussion

i. CON Standards

The relevant standard for inclusion in this section are specific to the determination there is a public need for the proposed services as demonstrated by certain factors, including, but not limited to:

- Whether, and the extent to which, the project will substantially address specific health problems as measured by health needs in the area to be served by the project;

- Whether the project will have a positive impact on the health status indicators of the population to be served;
- Whether the services affected by the project will be accessible to all residents of the area proposed to be served; and
- Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project.

ii. CONU Analysis

The CONU began its' analysis by analyzing the volume and demographic projections for the service areas that would utilize the proposed ASC. The bulk of services provided (urology, orthopedics, gastroenterology, ENT) would draw patients from a 23-zip code area near the proposed Topsham facility:

Municipality	Zip Code	County
Bailey Island	04003	Cumberland
Bath	04530	Sagadahoc
Bowdoin	04287	Sagadahoc
Bowdoinham	04008	Sagadahoc
Brunswick	04011	Cumberland
Dresden	04342	Lincoln
Durham	04222	Androscoggin
Farmingdale	04344	Kennebec
Freeport	04032	Cumberland
Gardiner	04345	Kennebec
Georgetown	04548	Sagadahoc
Hallowell	04347	Kennebec
Harpswell	04079	Cumberland
Jefferson	04348	Lincoln
Lisbon Falls	04252	Androscoggin
Orr's Island	04066	Cumberland
Phippsburg	04562	Sagadahoc
Randolph	04346	Kennebec
Richmond	04357	Sagadahoc
Topsham	04086	Sagadahoc
Whitefield	04341	Lincoln
Wiscasset	04578	Lincoln
Woolwich	04530	Sagadahoc

The Topsham ASC would be the closest facility that offers the proposed services in a non-hospital setting. The number of urology, orthopedics, gastroenterology and ENT cases is projected to grow from 26,339 cases in 2018 to a projected 30,474 cases in 2023 or 2.46%

annually. Due to an ongoing shortage of surgical specialists in the area of oncology and breast surgery the applicant utilized a larger 97-zip code area to project cases. The number of oncology and breast surgery cases is projected to more than double from 175 to 351 in the first two years of operation of the proposed facility.

CONU noted that the service area of the proposed Topsham ASC overlaps five different Maine counties. Due to the correlation between population growth and the need for new health care services, CONU analyzed population growth trends in these five Maine counties:

County*	2010 population	2019 population	% increase
Androscoggin	107,709	108,277	0.50%
Cumberland	281,690	295,003	4.70%
Kennebec	122,154	122,302	0.10%
Lincoln	34,445	34,634	0.50%
Sagadahoc	35,287	35,856	1.60%
TOTAL	581,285	596,072	2.54%

*Population increase from April 1, 2010 to July 1, 2019 per Census.gov/quickfacts

With the exception of Cumberland County which contains Portland (Maine's largest city), population growth is extremely low. It should be further noted that the population of Maine as a whole, has grown by only 1.2% during this same time period. This low population growth indicates that careful review is needed before introducing new infrastructure into the health care system. In response to a CONU information request, the applicant submitted a demographic analysis focusing specifically on the proposed Topsham ASC's 23 zip code service area where the ASC would expect most of its patients to reside. (This analysis was prepared by Stroudwater using IBM-Watson Health data). The current population of this service area is 107,790. In the next five years this population is expected to grow to 108,423 or .6%. Of note is the fact that the 0-17 age group is projected to decline by 3.8%, The 18-44 age group is projected to remain stable with a 0% growth rate while the 45-64 age group is expected to decline by 4.7%. The only group to see an increase in population is the 65+ age group which is expected to grow by 12.8%. These trends may negatively impact the proposed ASC. Commercial insurance revenue is projected to be 40% of the payor mix. A declining population in the 18-64-year-old age bracket would negatively impact revenues. A heavy reliance on the 65+ may be problematic as this age group may have a higher incidence of co-morbidities making them poorer candidates to receive care at an ASC. As previously discussed, the applicant is projecting a 12.3% increase over five years in urology, orthopedics, gastroenterology and ENT and a doubling of cancer procedures over the first two years of operation of the proposed ASC. These projected increases far exceed projected population growth in the service area. Also, of concern is that CMHC's utilization statistics are based on using 2 OR's and 2 procedure rooms. The additional 2 procedure rooms are going to be shell space for future expansion. At an 80% efficiency factor this means another 1,705 cases could be performed. The annual total cases performed could rise to 4,791. Although

the national trend of shifting from inpatient to outpatient settings continues, CONU is unsure if such a steep rise in procedures will occur when the population base in the area is growing slowly.

The applicant believes that a lack of affordable care and a convenient location are causing an outmigration from the area. The applicant cited a study from a Health Care Advisory Board stating that consumers choose a surgical provider based on two main factors, cost (53.2%) and travel time (19.8%). Although CMHC specifically stated that they did not factor outmigration into their projected statistics CONU believes it would be useful to determine treatment options available in, or in close proximity to the applicants 23 zip code service area. As shown below every municipality located within the applicants' service area is in close proximity to a full-service general hospital that offers similar services to the proposed ASC. Brunswick is home to Mid Coast Parkview, Portland contains Maine Medical Center and Mercy Hospital, Lewiston contains Central Maine Medical Center, St. Mary's and Central Maine Orthopedics (an ASC), while Augusta is home to MaineGeneral.

Municipality	Zip Code	County	Miles to Nearest Facility			
			Brunswick	Portland	Lewiston	Augusta
Bailey Island	04003	Cumberland	15	43	36	50
Bath	04530	Sagadahoc	10	34	27	31
Bowdoin	04287	Sagadahoc	12	36	15	28
Bowdoinham	04008	Sagadahoc	14	37	22	23
Brunswick	04011	Cumberland	0	28	22	34
Dresden	04342	Lincoln	23	46	27	18
Durham	04222	Androscoggin	13	27	11	39
Farmingdale	04344	Kennebec	30	52	30	8
Freeport	04032	Cumberland	10	18	17	39
Gardiner	04345	Kennebec	27	49	28	7
Georgetown	04548	Sagadahoc	20	44	37	40
Hallowell	04347	Kennebec	32	54	35	3
Harpswell	04079	Cumberland	9	36	30	42
Jefferson	04348	Lincoln	42	68	46	19
Lisbon Falls	04252	Androscoggin	12	30	10	32
Orr's Island	04066	Cumberland	12	39	32	46
Phippsburg	04562	Sagadahoc	17	41	33	38
Randolph	04346	Kennebec	30	51	30	8
Richmond	04357	Sagadahoc	23	44	22	19
Topsham	04086	Sagadahoc	7	36	22	28
Whitefield	04341	Lincoln	33	56	38	16
Wiscasset	04578	Lincoln	20	44	37	24

Woolwich	04530	Sagadahoc	11	35	28	30

While the applicant is correct that no ambulatory surgical center exists within this service area there are a multitude of multi-specialty surgical services available. However, the applicant lists a number of benefits to opening an ASC. ASC's reduce expenses for patients, insurers and Medicare. Patients typically pay less coinsurance for procedures performed in the ASC than for comparable procedures in the hospital setting. A growing body of research demonstrates exceptional outcomes in ASC's. In fact, the incidence of readmission to a hospital is less likely for patients receiving surgery at an ASC. ASC's have to meet extensive state and federal requirements and are reviewed regularly to ensure safety and quality. The ambulatory surgery center association states that the ASC health care delivery model enhances patient care by allowing physicians to focus exclusively on a small number of processes in a single setting, intensify quality control since ASC's have a smaller number of OR's, and allow patients more access to management. In summary, ASC's are growing in popularity because of safe and high-quality service, ease of scheduling, greater personal attention and lower costs. (Source: https://www.ascassociation.org/advancingsurgicalcare/aboutascs/industryoverview/apositivetrendinhealthcare)"

CONU utilized the Sagadahoc County 2019 Maine Shared Community Health Needs Assessment Report to determine specific health problems as measured by health needs in the area to be served by the project. Votes cast by community forums set priority areas within the County. The results are below:

Sagadahoc County Health Priorities

PRIORITY AREA	% OF VOTES
Mental Health	22%
Social Determinants of Health	17%
Access to Care	13%
Physical Activity, Nutrition and Weight	13%
Substance Abuse	11%
Older Adult Health/Healthy Aging	11%

One of the goals of the proposed Topsham ASC is to increase access to care by providing a low-cost multi-specialty surgical facility. This aligns with the access to care priority area outlined in the table above. Although this was listed as a priority, it is noteworthy that the percentage of the Sagadahoc County population that is uninsured was lower than the state overall (7.8% vs 9.5%) from 2012 – 2016. In addition, the percentage of Sagadahoc County's population who reported being unable to obtain health care due to cost was 6.7% in 2014-2016. This is significantly lower than the state overall (10.3%). The Gaps/Needs identified in the Sagadahoc County 2019 Maine Shared Community Health Needs Assessment Report follow:

. Mental Health
. Prenatal Care

. Chronic condition self-management
. MaineCare forms available for youth
. Points of contact for youth
. Accessibility of care
. Pediatric care for homeless youth
. Support for LGBTQ youth and education around the issues they face for all youth
. Consumer assistance for insurance
. MaineCare Expansion
. No insurance options for people who make too much to qualify for MaineCare.

Lack of access to care is mentioned as a health care need in the area, however CONU believes there are many facilities offering multi-specialty surgical care services in close proximity to the proposed Topsham ASC. Although the applicant states that the Topsham ASC would provide a low- cost option it does not provide comparative pricing/cost data to Mid Coast Parkview Health's surgical unit (located approximately seven miles from the proposed Topsham ASC) or other nearby hospitals offering these services. This comparison would have determined if there was a significant difference in cost between these two facilities. Another important factor in determining need is to explain why patients out migrate from this area to receive care. Is it to get access to less expensive care as the applicant state or are there clinical and consumer preference reasons for this outmigration?

CONU has demonstrated that there is a wide array of hospital affiliated multi-specialty surgical care in, or in close proximity to, the proposed Topsham ASC and the surrounding 23- zip code service area. These hospitals provide advanced support for the full range of services from surgery to intensive care. Often hospitals are required by regulation to provide necessary and essential services 24 hours a day, 7 days a week, that negatively impact their bottom line. In order to continue providing these vital services hospitals need to rely on surgeries and other complex procedures to achieve a positive operating margin. CONU does not believe that this project will have a positive impact on the health status indicators of population to be served. The service area of this project already has numerous alternative treatment sites and has a low rate of population growth. Introducing additional healthcare infrastructure into this market will result in a shift in profitable services from hospitals to the ASC, negatively impacting their bottom line. This coupled with the devastating impact of COVID 19 will limit hospitals ability to provide necessary services.

The applicant identified the prevalence of cancer in the service area as a specific health problem in the service area. As stated previously, the applicant received CON approval for a project to replace and enhance the existing, oncology services provided at the CMMC campus in Lewiston. This project involved bringing together two essential outpatient subspecialties- radiation and medical oncology in to one locale. The applicant is an investor in Central Maine Orthopaedics located in Auburn, Me.

The applicant states that the services affected by the project will be accessible to all residents of the area proposed to be served. To support this assertion the applicant provides a chart showing that they will provide services to Medicare and Medicare services at a higher level than the

national medium for ASC's. In addition, CMHC provides financial assistance to patients based on income levels and would continue this practice at the proposed Topsham ASC.

The applicant states that this project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project. ASC's have lower infection rates than hospitals and have care that is more efficient and takes less time. OR's would have a shorter turn-around time because they don't have to deal with disruptions associated with emergency cases.

Directly Affected Party Comments:

CMHC declares there is a public need for its project but neglects to account for the presence of Mid Coast – Parkview health just minutes away. In fact, MCPH has ample capacity for any growth in outpatient surgeries, enough to absorb even the inflated projected volume CMHC claims it will address with its proposed project. Critically, MCPH already provides these services at high quality and low-cost relative to the rest of the state. CMHC relies on its "outmigration analysis" to demonstrate need. But the "analysis" fails to provide any information to explain why patients seek care out of their local area or demonstrate where patients go for care. There is no information that would allow a conclusion that patients leave the local area despite MCPH's capacity because they seek a lower price or because they are concerned about quality, the two things constituting a supposed "public need" that CMHC claims its proposed project will address. Put simply, the proposed ASC is not needed and would only serve to add needless overhead to the healthcare infrastructure in Southern Midcoast Maine. The application fails to demonstrate otherwise.

Post Technical Assistance Meeting Additional Information – Public Need

Growth Projections

When planning the proposed Topsham ASC, CMHC considered how health care is being utilized today and how that is expected to change in the southern mid-coast market. While the US Census Bureau projects a relatively flat 0.6% population growth rate over five years, the growth in population is not the only, or in fact the best, metric to understand the changing health care needs of the community. There are more relevant factors widely acknowledged in the health care industry that affect health care utilization including population aging, local community variations in care, advances in technology, and changing care practices such as the shift in care from the inpatient to outpatient setting.

As described in CMHC's application and echoed in public comments and at the public hearing, CMHC used a reputable and sound method to study the public need for the Project. Relying on data from the Maine Health Data Organization (MHDO), Truven Analytics/IBM Watson, and with the assistance of Stroudwater Associates, CMHC analyzed the need for outpatient surgical services in its service area, including the defined service area for the proposed ASC, and determined that there is a demonstrated need for three ORs to serve the projected incremental growth in surgeries (see CMHC's responses dated 09/30/2020 to request for additional information pg.10). Truven IBM Watson projected 12.3% growth in utilization over five years for the proposed services.

In short, the service area for the proposed ASC has a population of 107,790 with approximately 21.2% of the population being 65 or older. This highest utilizing segment of the population, seniors, is projected to grow by 12.8% and comprise 23% of the services area's population by 2025. As Bill Caron, the CEO of MaineHealth, noted in published comments from January 2020, Maine is already the oldest state in the country and "if you look at demand, that's going to continue to grow in 2020. The older age cohorts will require more services."[4] This Project is designed to meet the growing need for outpatient surgical services generated by a growing senior population with higher utilization rates as a result of the natural process of aging.

Cost is a Barrier to Access to Health Care and this Project is Explicitly Targeted to Overcome the Cost Barrier

The public need for this Project is also evidenced by the wide-spread support for the lower-cost setting offered by the ASC. As both Peter Hayes (President of the Healthcare Purchasers Alliance) and Andrew Ellis (Vice President at Anthem of Maine) testified in the public hearing, Maine is the oldest state in the nation, has some of the highest health care costs, and has one of the lowest average incomes in the nation (see public hearing transcript pg. 37). MaineHealth's assertion that "the proposed ASC will cause a negative financial impact between $10 and $15 M annually" is in fact an admission about the cost differential between hospital-based services and those in a freestanding ASC. The ASC is expected to generate only $7M annually. Simply put, services that generate $10 to $15M in revenue in a hospital setting generate only $7M in a freestanding ASC setting. The reality is that this Project provides for a high-quality setting at a much lower cost than what patients currently have available in the community. This cost differential itself evidences the public *need* for the Project in the community.
The Project will offer the surrounding communities' access to choices that will improve their outcomes and lives by lowering the economic barriers to timely, local and comprehensive outpatient surgical care. Patients with high insurance deductibles are paying more than they can afford for care at a time when 69% of Americans have less than $1,000 in their savings account. The result is patients responding by forgoing *needed* care. An example of this was provided by Topsham Family Medicine provider Dr. Dave Salko who relayed the story of a patient who had delayed a colonoscopy due to cost. By the time Dr. Salko's patient completed a colonoscopy, his cancer had spread (see Dr. Dave Salko letter of support).[5] As Dr. Salko noted, "the additional money needed for an earlier diagnosis and a better outcome was small, but at the time it presented a financial barrier to health."

The data and research provided in the application and at the public hearing that established an unmet need in the community are further reinforced by letters of support from community members, local unions (BIW local S6, S7, and district council), existing patients of Central Maine Healthcare, employers (see the letter from Robbins Lumber providing an example of an employee who travels 45+ minutes for lower-cost care), payers, health care purchaser's alliance, state legislators, and local community providers (both independent and employed by CMHC)

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[4] https://www.mainebiz.biz/article/20-on-20-health-care-may-be-entering-a-critical-convergence-of-trends

[5] Also featured in the press herald on 08/18/2020 https://www.pressherald.com/2020/08/18/guest-column-proposed-topsham-surgery-center-would-help-patient-care-experience-cost/

mentioned above. The need for lower-cost outpatient surgical services has been demonstrated through reputable data analytics, national health care trends, and community support. The community is asking for lower-cost outpatient surgical services. The evidence in the record demonstrates that the community wants to fill the unmet need for low-cost outpatient surgical services that will start to positively impact the high health care costs in the state that act as barriers to receiving routine and preventative care. CMHC is responding to this gap in care and requests from the community with a proposal to fill this unmet need and change the face of health care for the better.

MaineHealth's Claims of Capacity at Its Brunswick Hospital Are Not Relevant to the Determination of Public Need for the Project

In order to establish the public need for a proposed project, a number of criteria must be considered, none of which includes the self-reported capacity of an existing competitor. In addition, MaineHealth's self-reported utilization numbers for its Brunswick hospital pose more questions than answers. The self-reported OR utilization increased from 30% to ~40% from 2017 to 2018 and from 40% to ~46% from 2018 to 2019. Suddenly, from 2019-2024, this trend shows much lower growth despite national trends of procedures shifting to an outpatient setting and an aging population that requires more services. While CMHC cannot explain why MaineHealth's Brunswick hospital has such low OR utilization, the current and projected utilization reported by MaineHealth bucks health care and utilization trends. The decline may be attributable to a variety of factors, including outmigration from Brunswick to MaineHealth's other facilities, including Maine Medical Center in Portland, physician preferences and scheduling. MaineHealth's track record of market share shifts to Portland after the acquisition of member hospitals poses a more material and direct threat to the volumes at MaineHealth's Brunswick hospital than this ASC[6]. In any event, there is no evidence that the proposed ASC, which is not in operation, has any causal connection to the declining OR utilization trend at MaineHealth's Brunswick hospital. For all of these reasons, MaineHealth's claims of a causal connection between the Project and the low OR utilization at MaineHealth's Brunswick hospital should be dismissed.

CONU Response to Post Technical Assistance Meeting Additional Information:

Although providing low-cost surgical services is a laudable goal, CONU is not convinced that adding additional infrastructure to the Mid Coast area is serving a public need. Further, CONU is not convinced that there is a lack of low-cost multi-specialty surgical services in the area, there are a number of full-service hospitals in the region that already provide these services. Comparative cost data for the proposed facility and nearby facilities was not provided by the applicant. As shown by the applicant, Mid Coast Parkview's utilization statistics show occupancy of less than 50% even with the national trend of increasing utilization of outpatient services. This apparently low utilization of Mid Coast-Parkview hospital needs to be addressed by the applicant. The low population growth in this region and the State of Maine as a whole, shows that careful consideration must be given before approving additional services. This project

[6] As identified in a memorandum submitted by Stroudwater Associates on September 30, 2020 (see ASC CONU Written Responses September 20, 2020)

would immediately add 2 OR's and 2 Procedure rooms to infrastructure in the region with shell space for 2 more rooms. This would significantly increase capacity in a region that does not appear to need it based on occupancy and demographic statistics. Even with the rate of growth predicted by the applicant, it appears that Mid Coast Parkview has the capacity to absorb this growth in the need for services There are benefits associated with the ASC, however, disruptions in patient volume and revenues at nearby hospitals may negatively affect quality and outcome measures of patients served by these hospitals. Introducing additional healthcare infrastructure into this market will result in a shift in profitable services from hospitals to the ASC, negatively impacting their bottom line. This coupled with the devastating impact of COVID 19 will limit hospitals ability to provide necessary services that are not profitable. CONU believes that Topsham is not the primary health service area of CMHC, and the introduction of the Topsham ASC would disrupt the existing health care providers in the area, particularly Mid Coast – Parkview Health which is located within 7 miles of the proposed Topsham ASC. The applicant states that there is an outmigration of patients from the area due to a lack of low -cost services, CONU believes that there may be clinical reasons or consumer preference reasons why patients choose to utilize services outside of the Mid Coast area.

iii. Conclusion

The Certificate of Need Unit recommends that the Commissioner find that the applicant has **NOT** met their burden to show that there is a public need for the proposed project.

V. Orderly and Economic Development

A. From Applicant

A. Impact on Health Care Expenditures

The Topsham ASC is projected to produce significant savings in overall health care expenditures in the State. The projected savings will be achieved by providing outpatient surgical cases in a freestanding setting as compared to a hospital outpatient department amounts to $3,050,000 (rounded) in Year 1 and $6,261,000 (rounded) in Year 2.[7] The current locations available for these services in this market are hospital outpatient department rates, which trend 47% higher than the rates expected at the Topsham ASC. Importantly, the projected volume at the Topsham ASC will largely come from organic growth in the market as documented by IBM Watson projections. Without the Topsham ASC, a larger percentage of outpatient surgeries will likely be performed in more expensive hospital-based outpatient department settings. The availability of a low cost, geographically accessible option will result in lower overall health care expenditures.

There are six ASCs currently operating in Maine that overlap with specialties to be provided at the Topsham ASC. The Topsham/Bath/Brunswick area is the largest market in the State without an ASC. As a result, patients and payers incur higher costs for procedures that otherwise can be performed in an ASC. Government payers are expected to comprise 52% of the cases between Medicare, Medicaid and Managed Care. Medicaid alone pays for at least 7% of the cases. Based on the expected revenue from Medicaid of $137,503 in 2022, the state would realize a savings of $121,937[8] in the first year if the procedures were performed in an ASC setting. Over the first five years of operation of the Topsham ASC, total state savings by services being provided are expected to total over $1,099,900 (rounded). This savings aligns with the Governor Mills' current goal of tackling the affordability and accessibility of health care for hardworking, middle-class Mainers (Mills, 2019).

In the last few decades, there has been significant consolidation among Maine hospitals. In many instances, this consolidation has resulted in increased outmigration from the service area. The Topsham ASC would provide an alternative option and an opportunity to retain more care in the service area, avoiding the burden of travel for patients and potential erosion of clinical service capabilities in the region.

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[7] Savings are based on the difference between HOPD versus assumed ASC rates (47% less) applied to the total number of cases in years 1 and 2. 47% difference is based on the top CPT codes for each specialty using Medicare OPPS and ASC rates. In Year 1, 1,558 cases will be performed at a weighted average rate of $2,208 compared to an HOPD rate of $4,167. Total Year 1 savings are $1,958 per case, or $3,051,223 in total. In Year 2, 3,119 cases will be performed at a weighted average rate of $2,265 per case compared to an HOPD rate of $4,273. This conservatively assumes that HOPD rates will receive a similar incremental increase as ASC rates. In Year 2, savings are $2,008 per case, or $6,264,852 in total.

[8] Year 1 savings are based on a rate differential of $1,118 per case applied to 109 Medicaid cases.

Nationally, there are hundreds of markets that are served by both ASCs and local hospitals. Providing a lower cost, safe option for care delivery is good for consumers and payers and is compatible with the continued operation of a full-service hospital in the vast majority of cases.

The significant cost benefit of this option to consumers and payers, including employers and the state, can be gleaned from the Procedure Price Lookup tool published by CMS; Medicare allows consumers with Medicare to view the national average payments to HOPDs (hospital outpatient departments) and ASCs for numerous procedures. Outlined in Table 8 below are the differences in average patient out-of-pocket costs for several common procedures.

Table 8: Average Patient Out of Pocket Costs. *Source: Procedure Price Lookup, 2020, Statute of Maine Department of Health & Human Services.*

Procedure	Patient Average Out of Pocket Cost in ASC	Patient Average Out of Pocket Cost in HOPD	Payment Difference
Colonoscopy	$100	$195	$95
Arthroscopy, Knee	$251	$524	$273
Biopsy of Prostate Gland	$157	$347	$190
Partial Removal of Breast	$211	$563	$352
Total Removal of Breast	$418	$983	$565

In terms of the total cost of care that would be reimbursed by Medicare in combination with the cost to the patient, Maine ASCs have lower average costs of service than the national average for ASCs and HOPD rates (Table 9).

Table 9: Total Cost of Care. *Source: Procedure Price Lookup, 2020, State of Maine Department of Health & Human Services.*

Procedure	Average Total Cost in Maine ASC (2018)	Average Cost Total Cost in ASC (National)	Average Total Cost in HOPD (National)
Colonoscopy	$450.42	$504	$979
Arthroscopy, Knee	$1,181.87	$1,256	$2,623
Biopsy of Prostate Gland	$719.87	$785	$1,739

Partial Removal of Breast	$951.07	$1,057	$2,816
Total Removal of Breast	$1,889.30	$2,094	$4,915

In the State of Maine, for common outpatient procedures, costs across procedures are 43% less in an ASC setting. As shown in Table 10 below, only skin growth removals are less expensive in hospital locations in Maine.

Table 10: Maine Outpatient Procedure Prices Per Location. *Source: CompareMaine.com.*

Outpatient Procedure	ASC	Hospital
Remove skin growth (premalignant/precancerous)	$ 379	$ 201
Surgical arthroscopy of knee	$ 5,242	$ 10,038
Surgical arthroscopy of shoulder	$ 9,066	$ 16,404
Grand Total	$ 5,706	$ 8,162

B. Availability of State Funds to Cover Any Increase in Cost

No state funds will be required to support the proposed project because it is expected to reduce overall health care expenditures. Government payers are expected to comprise 52% of the cases at the Topsham ASC. Medicaid alone is expected to account for at least 7.0% of the cases. Based on the expected revenue from Medicaid of $137,503 in 2022, the State would realize a savings of $121,937[9] in the first year of the Topsham ASC's operation. Over the first five years of the Topsham ASC, total State savings for the services being provided are expected to total over $1,099,937[10].

Government payers are assumed to provide $1,203,814 in revenue in Year 1 and $2,452,603 in Year 2. This represents a savings of $1,067,000 in Year 1 and $2,175,000 in Year 2 compared to the cost of these cases if they were performed in an HOPD setting at HOPD rates. Over the first five years of the Topsham ASC, total savings for government payers is expected to total over $10,128,000.[11]

C. Potential for More Effective, More Accessible or Less Costly Technology to Be Available

[9] $121,937 savings are based on 109 Medicaid cases at ASC rates (47% less) compared to HOPD rates.
[10] $815,000 savings are based on total Medicaid cases in the first five years (1,379 total cases) multiplied by the difference between ASC net patient service revenue per case and HOPD-level rates.
[11] Total cases assumed over the first five years to come from government payers are 5,628. In Year 1, average rate for government payers is assumed at $1,502 per case compared to $2,835 in an HOPD setting. Year 1 case rate represents a savings of $1,333 per case, or $1,067,733 in total based on 801 cases.

ASCs are the higher quality, more accessible and less costly alternative to hospital settings for the proposed outpatient surgical services (*See* Table 9). They enable the patient to schedule his/her procedure for a specific time, guarantee at most a 23-hour stay, and pay a lower cost. Nationally, there is an increasing shift from inpatient to outpatient care. Admissions to hospitals per 1,000 individuals have dropped nationally from 117 in 2007 to 105 in 2017 (10% decrease) (Kaiser Family Foundation, n.d.). Maine has followed this trend, dropping from 115 admissions per 1,000 individuals in 2007 to 96 in 2017 (16.5% decrease) (Kaiser Family Foundation, n.d.). These numbers indicate that patients are seeking care outside of a hospital setting. Outpatient visits per 1,000 people have increased nationally from 2,000 in 2007 to 2,352 to 2017, a 17.6% increase in 10 years (Kaiser Family Foundation, n.d.). Maine has also followed this trend from 3,569 visits per 1,000 individuals in 2007 to 4,475 visits per 1,000 individuals in 2017, a 25% increase over ten years (Kaiser Family Foundation, n.d.). ASCs are capturing the transition of procedures and surgeries from an inpatient to outpatient setting. Each year more procedures and CPT codes are approved to be performed in an ASC setting as a result of this transition from an inpatient to an outpatient care setting. According to the 2018 Ambulatory Surgery Center Market Report by the Health Industry Distributors Association, surgery center growth is on track to rise 16% through 2026 (Health Industry Distributors Association). CMHC wants to provide this affordable, growing service to patients in its service area and surrounding regions because it is the least costly alternative available and reflects the future of health care.

Alternatives to the Project

The alternatives that were evaluated as part of the planning process for the Topsham ASC include the following:

I. **Do nothing:** The community lacks a low cost option; consumers and payers fund the estimated burden created by the lack of a lower cost option equal to approximately $3,050,000 (rounded) in Year 1 and $6,261,000 (rounded) in Year 2.[12] Without the proposed ASC, consumers lack in-market access to lower cost specialty services and will continue to seek care outside of the service area as shown in Table 4: Outmigration Analysis. No other system has proactively provided an ASC option. This option also provides no new capacity for additional projected volume, which means that cases would not be able to be retained in the region. The result would be additional travel burden on patients and a missed opportunity to add choice and clinical capabilities in the Southern Mid-Coast Region. Although a hospital could potentially address the need for additional capacity to meet projected volume growth in the region, patients, employers, payers and providers would not receive the benefit of a high quality, low cost option in the region. In future years, the lack of a local, cost-effective option would represent a continuing burden on patients, providers, payers and employers in the Southern Mid-Coast Region.

II. **Rely on out of market capacity:** This option would force patients from the region to travel for care and does not result in additional local options for providers or patients.

[12] Savings based on the difference between HOPD versus assumed ASC rates (47% less) applied to the total number of cases in years 1 and 2. See Section V.A.

Outmigration would be expected to increase, and local clinical capabilities would not be able to grow and would likely deteriorate due to the loss of patients and cases to out-of-market providers. Further, the potential cost savings would be degraded by not providing an additional low cost, high quality point of access.

III. **Build the proposed Topsham ASC.** This option retains care locally, provides a low-cost option for patients and providers, and strengthens local clinical capabilities as a result of retaining more cases in the region. The ASC is needed to address the projected volume increases and will address them in a safe, high quality, low cost care setting.

B. CONU Discussion

i. CON Standards

Relevant criteria for inclusion in this section are specific to the determination that the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State as demonstrated by:

- The impact of the project on total health care expenditures after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;
- The availability of state funds to cover any increase in state costs associated with utilization of the project's services; and,
- The likelihood that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available.

ii. CON Analysis

This project involves the expenditure of approximately $16.5 million dollars to construct a new Ambulatory Surgical Center in Topsham, Maine. Ambulatory Surgical Centers compete directly with hospital outpatient departments for many medical procedures that can now be performed in an outpatient setting. The result of this competition is to divert profitable surgical cases from the hospital to the ASC, thus decreasing hospital revenues that subsidize the hospitals unprofitable but vital community services (emergency room care, free care, health screenings and community outreach among others). This is particularly concerning for this proposal because the proposed ASC would be located within seven miles of Mid Coast – Parkview Health. The negative effect of shifting profitable services away from hospitals will be further magnified by the economic downturn caused by the COVID 19 pandemic. A slowing economy increases the demand for safety net services due to unemployment and lack of insurance. According to a 2015 Lehigh University study, The Financial Impact of Ambulatory Surgery Centers on General Surgical Hospitals the emergence of ASC's causes hospitals to treat more severely ill patients with more intensive treatments that drive up operating costs, resulting in a decrease in profit margin.

CONU believes a significant increase in state costs associated with utilization of the project's services would occur due to the additional infrastructure associated with the project and the need to provide a large volume of services to achieve positive operating results. More worrisome to CONU is the shift in service volume and revenues between existing providers and the proposed Topsham ASC.

CONU also examined the ASC market in the State of Maine:

Facility	Location	Type of Surgery
Bangor Eye Surgery, PA	Bangor	Eye Surgery
Central Maine Eye Surgery Center, LLC	Lewiston	Eye Surgery
Central Maine Orthopaedics	Auburn	Orthopaedic Surgery, Podiatry
Coastal Eye Surgery Center, LLC	Ellsworth	Eye Surgery
Downeast Surgery Center	Bangor	Orthopaedic and Plastic Surgery
Eye Care of Maine ASC	Waterville	Eye Surgery
Eyecare Medical Group	Portland	Eye Surgery
Intermed Surgery Center	Portland	Gynecology, Laparoscopy
Maine Eye Center	Portland	Eye Surgery
NMOFS Ambulatory Surgical Center Pc	Presque Isle	Oral and Plastic Surgery
Oa-Centers for Orthopaedics	Portland	Orthopaedic Surgery
Portland Endoscopy Center	Portland	Endoscopy Procedures
Vision Care of Maine, LLC – Bangor	Bangor	Ophthalmology
Vision Care of Maine – Aroostook LLC	Presque Isle	Ophthalmology
Western Avenue Day Surgery Center	South Portland	Plastic & Hand Surgery
Wolf Eye Care *		

*Wolf Eye Care changed its name to Central Maine Eye Surgery, LLC.

CONU notes that ASC's in Maine tend to be owned/co-owned by physicians and corporate partners such as Covenant Surgical Partners, Inc in the case of Central Maine Eye Surgery Center, LLC and Coastal Eye Surgery Center, LLC or Spectrum Healthcare Partners in the case of Central Maine Orthopaedics and OA Centers for Orthopaedics. The ASC's tend to be very specialized, niche providers of services. This differs from the proposed Topsham ASC which proposes to provide a wide array of services such as Gastroenterology, Orthopaedics, Breast, Urology and ENT services. This presents a problem because taking a larger array of profitable services from a hospital will increase the negative impact on hospital finances and will create a problem in recruiting specialists in an area that already suffers from a shortage of surgeons.

The applicant considered and rejected two alternatives for the following reasons:

A) Do nothing. The community would lose out on a high-quality, low-cost option for multi-specialty surgical services.
B) Rely on out of market capacity. Would require patients to travel for care. Care would not be improved in the local community.

CONU notes that high quality multi-specialty services already exist in the service area and close to the service area. Introducing additional infrastructure into the existing healthcare market would result in additional costs added to the system. As shown in the public need section of this analysis, there are multiple options within close proximity to the proposed ASC.

CONU believes that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available. Office-based surgery (OBS) may become a serious competitor of Ambulatory Surgical Centers. Just as volume has shifted from inpatient to hospital outpatient departments and then to Ambulatory Surgical Centers, OBS is seeing rising volumes in the areas of gynecology, ENT, ophthalmology and plastic surgery. CONU further believes that other alternatives should be considered by the applicant such as collaborating with other service providers (such as CMHC's investment in Central Maine Orthopedics) to identify a niche that is not being served in the area. This would have the advantage of sharing expertise and resources and, due to a smaller footprint, would be less disruptive to the service area.

Directly Affected Party Comments:

This proposal brings not the prospect of orderly and economic development required under the law, but the opposite. CMHC in its own public testimony sees itself as a change agent and disruptor in the healthcare industry in Maine. Its goal is to "cherry pick" profitable procedures in the Southern Midcoast Region and send those dollars to Lewiston, propping up its bottom line at the expense of another community.

And the costs in that community would be felt directly. Although hampered in its projections by a lack of detail in CMHC's application, MCPH estimates that it would suffer between $10 million - $15 million in revenue annually as a result of this facility being built. As we all know, nonprofit hospital systems like MCPH provide necessary and essential services that lose money and remain viable only because they also provide services that make money, like surgeries and other complex procedures. CMHC's own application and statements to the press make it clear that the proposed project located outside CMHC's primary service area and at the outer edge of tis total catchment area is designed to pull profits from the spoke (Topsham) to increase the profitability of the hub (Lewiston), all at the expense of the people served regardless of "profitability" by MCPH in its primary service area. If CMHC's application is approved, MCPH would undoubtedly be faced with the choice of either raising prices for other services or, quite possibly, eliminating services to make up for the losses it would suffer.

Post Technical Assistance Meeting Additional Information -Orderly and Economic Development

Potential Impact to Health Care Expenditures

The Project will reduce the overall cost of care by bringing a missing care setting to the Topsham-Brunswick-Bath community. The result will be to produce savings in overall health care expenditures in the State. CMHC specifically sized this facility around growth assumptions that reflect organic growth in utilization in the community for procedures that can safely be performed in an ambulatory surgical center setting. As discussed in the "Public Need" section, MaineHealth's self-reported OR utilization for its Brunswick hospital is irrelevant to the statutory criteria to be applied to evaluate the proposed freestanding ASC. While CMHC is in agreement with MaineHealth that operating a hospital-based OR and an OR at a freestanding ASC are functionally similar in operations, the cost differential presents an apples to oranges comparison between the two care settings. CMHC is proposing a freestanding ASC to address the need for access to convenient, high quality, lower-cost surgical services that MaineHealth has not provided to the community.

Care Will Be Accessible to All Residents

As CMHC's Chief Financial Officer (CFO), John Whitlock, testified at the public hearing (see public hearing transcript pg. 8 – 12), CMHC will provide free care (assumed as 1.7% of gross charges) at the Topsham ASC. This percentage is in fact higher than what MaineHealth's Brunswick hospital provided in 2018 (1.2% of gross charges). Further, as outlined in the application, the proposed Topsham ASC is projected to have a higher percentage of patients insured by governmental payers (42.2% Medicare and 9.8% Medicaid) as compared to MaineHealth's Brunswick hospital (32.8% Medicare and 7.8% Medicaid). Any assertion by MaineHealth that CMHC does not plan to provide access to the ASC to all residents is contrary to CMHC's commitment in its CON application and public testimony.

CONU Response to Post Technical Assistance Meeting Additional Information:

CONU disagrees with the applicant that Mid Coast Parkview's utilization is irrelevant to either the public need section or the orderly and economic development section. One of the key purposes of the CON statue is to support reasonable choice in health care services while avoiding excessive duplication. Since the applicant has not demonstrated a public need for additional surgical services in the region this additional infrastructure could add costs to the overall health system. This new infrastructure would need to provide a large volume of services to achieve positive operating results. Due to the interdependent nature of Maine's healthcare system it is necessary to look at the impact of a project on healthcare system as a whole to avoid costs of new services exceeding their benefits.

iii. Conclusion

CONU recommends that the Commissioner find that the applicant has **NOT** met their burden to demonstrate that the proposed project is consistent with the orderly and economic development of health facilities and health resources for the State subject to including the recommended condition.

VI. Outcomes and Community Impact

A. From Applicant

A. High Quality Outcomes

The quality scores of the Auburn ASC demonstrate CMHC's ability to deliver high quality outcomes for patients in an ASC setting and indicate that the Topsham ASC can also deliver these same high-quality outcomes for patients in the Southern Mid Coast Region. The Auburn ASC quality report for 2019 has a clinic patient satisfaction rate of 99.0% compared to a benchmark of 80.60% and an ASC patient satisfaction of 98.3% compared to a benchmark of 94.50%. Furthermore, CMHC's hospitals have earned four consecutive "A" grades in LeapFrog--a key quality indicator and demonstration of providing high quality services to the community.

The cost comparison from Compare Maine for a surgical arthroscopy of the knee shows a cost of $4,688 compared to the state average of $6,625 and a surgical arthroscopy of the shoulder for $9,786 compared to the state average of $12,270. The current hospital transfer or admission for the Auburn ASC is 0%. CMHC will utilize its proven track record to keep patients safe and provide high quality outcomes.

CMHC plans to utilize a seasoned ASC manager to implement best-practice protocols at the proposed Topsham ASC. The Topsham ASC will establish quality standards based on national standards and utilize a quality scorecard mechanism to track performance against these standards. The use of a rigorous quality scorecard will enable the ASC to ensure it delivers high quality outpatient surgical services. This will also be evaluated on a consistent basis by a quality committee. Further, the proximity between the Topsham ASC and the current CMHC physician offices will improve care coordination, allowing for easy access to follow-up visits, and enhancing overall communication between patients, physicians, and the rest of the care team. The Topsham ASC can achieve the best outcomes for patients through well-coordinated care that is easily accessible to patients.

B. No Negative Effect on Existing Service Providers' Quality of Care

As addressed in Sections III.B and IV.A, the proposed ASC is tailored to meet the future utilization needs of the community and the projected additional cases in the service area. Therefore, it should not affect the existing caseloads of providers currently in the market or the quality of care delivered by existing providers. An ASC will allow more individual providers to remain in the service area, including valued specialists in short supply, and reduce the travel time for patients and physicians. Frequent travel by providers and non-patient care time are cited as factors that can lead to provider burnout. Preventing burnout in physicians has been shown to increase the quality of care provided to patients.

B. CONU Discussion

i. CON Standards

The relevant standard for inclusion in this section is specific to the determination that the project ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers.

ii. CON Analysis

The purpose of this project is to build an ambulatory surgical center in Topsham, Maine to provide new treatment capabilities, operational efficiencies, improved access, and a safe, high quality patient experience. This project does not address a current need and will cause a shift in market share that would adversely affect the quality of care delivered by existing service providers or other facilities.

As previously discussed, the applicant has not operated an ambulatory surgical center. The applicant has not fully described any deficiency in the quality of care being provided and has demonstrated why this project would improve quality outcomes as some of the public comments suggest. The standard is to ensure quality is not impacted. The directly affected party claims that the volume of certain proposed services would make it more likely that the current services could not be maintained at its current levels of offerings; indirectly affecting quality by removing service levels, i.e. emergency 24-hour services.

CONU does not believe that there is a likelihood of higher quality outcomes arising from this project.

As seen below the directly affected party has mentioned that there may be an impact on the services provided at the local hospital because of a decrease in service utilization this would have the potential to decrease the availability of hospital-based services. It is the obligation of the applicant to demonstrate if this is significantly true or not.

Directly Affected Party Comments:
The project would negatively affect outcomes and community impact. The proposed surgery center would siphon off procedures in certain specialties, and the result is that MCPH would lose the critical mass needed to sustain enough providers of those services to offer 24-hour emergency specialty care. So, for instance, if the CMHC center takes away colonoscopies and we have only enough work to keep two gastroenterologists busy instead of the current three, that won't be enough doctors to maintain a call schedule. Patients needing emergency gastroenterology care will have to go to Portland to get it.

Post Technical Assistance Meeting Additional Information -Outcome and Community Impact

Impact on Community Providers

The proposed ASC will not negatively affect the quality of care delivered by any existing service provider. In fact, multiple community providers have provided written letters of support for the Project indicating that it will improve quality and fill an existing gap in the community for outpatient surgical services that their patients need. These providers include:

- New England Cancer Specialists--an independent oncology group providing services at the Topsham Care Center
- Martin's Point Health Care--one of the largest independent primary care providers in the state
- Coastal Orthopedics--an independent Orthopedic group in Brunswick, Maine
- Casco Bay Physical Therapy--providing services in Topsham, Maine
- Shields Healthcare--providing imaging services in Topsham, Maine
- CMHC existing providers:
    - Topsham Family Medicine
    - Maine Urgent Care
    - Topsham Care Center Specialists

All of these existing providers serve patients in the Topsham-Brunswick-Bath community. CMHC's own existing providers will extend the continuum of care to their existing patients and offer outpatient surgical services that patients would otherwise need to obtain from a new provider or travel to Lewiston.

MaineHealth contends that the Project will negatively impact its *volume*, but this is not an appropriate consideration under the Certificate of Need statute. As indicated above, the Certificate of Need statute assesses whether a project negatively affects the *quality* of care of existing service providers. It is nothing but a stretch for MaineHealth to contend that 2 ORs will negatively affect the quality of care provided by the system's Brunswick hospital. Just as an urgent care center will not negatively affect the care provided at a hospital, the proposed ASC, with 2 ORs and 4 procedure rooms will not affect the quality of surgical services at MaineHealth's Brunswick hospital. Rather, the Project is responding to an unmet and growing need in the community, among a variety of health care providers and patients, for low-cost and high-quality outpatient surgical care in the southern mid-coast region. MaineHealth's response indicates that rather than allowing consumers to benefit from competition in the health care marketplace, the $2.5 billion system will threaten cutting services or raising prices

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Project is Strengthening Services in CMHC's Existing Service Area

CMHC is proposing to continue its longstanding commitment to the Topsham-Brunswick-Bath community and expand choices for Maine people, including CMHC's existing patients, that will help keep costs down. MaineHealth's narrative that CMHC's proposal should be rejected on the basis that CMHC is based in Lewiston ignores not only the statutory criteria for approval under the Certificate of Need statute but also the fact that CMHC's service area has included the Topsham-Brunswick-Bath area for over a decade. It also ignores the fact that MaineHealth is a $2.5 billion corporation based in Portland whose claim to the service area has only lately been acquired through its takeover of the previously independent local hospital. As State Senator Nate Libby, Senate Majority Leader at the time of submission, noted in his letter of support, "MaineHealth has bought up hospitals and practices throughout the state, and expanded their

footprint in opening new services that even reach into New Hampshire.... If we are not careful, and we squash smaller hospital systems, Maine will be left with only one corporate hospital alternative." CMHC is proposing to continue a commitment extending over a decade to the Topsham-Brunswick-Bath community and expand choices for Maine people that will help keep costs down.

CONU Response to Post Technical Assistance Meeting Additional Information:

The applicant cited community and healthcare provider support for this project in the above paragraph. CONU also has received numerous comments against this project.

CONU does not believe that the applicant has sufficiently evaluated the impact of its' project on existing service providers in the Mid Coast region. In order to meet the requirements of this section the applicant must demonstrate that the proposed project does not negatively affect the quality of care delivered by existing service providers. As stated throughout this analysis the services proposed in this project are profitable services which are necessary to support a hospital's bottom line so that it can provide necessary and statutorily required services that are not profitable. If multi-specialty surgical services are performed at the proposed ASC this will impact the hospital's ability to provide necessary care and negatively affect the quality of care delivered by existing service providers to the community as a whole.

iii. Conclusion

CONU recommends that the Commissioner find that the applicant has NOT met their burden to demonstrate that this project will ensure high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers.

VII. Service Utilization

A From Applicant

A. Risk of Inappropriate Increases in Service Utilization

This project will not result in inappropriate increases in service utilization. Projected utilization growth for the Southern Mid-Coast Region based on organic growth alone will require three additional ORs for outpatient surgical services by 2023 (*See* Section III.B.). The ASC will fulfill an existing need for outpatient surgical services for patients, especially those with high-deductible health plans, in a high quality, low cost setting. The estimated number of outpatient surgical procedures for gastroenterology, orthopedics, ENT, and urology for the population in the service area are projected to increase by 9% or 16,104 individuals from 178,786 to 194,889 by 2023 (IBM Watson, 2020). Services related to surgical oncology and breast health are projected to increase from 524.5 cases to 534.6 cases in 2023 (IBM Watson, 2020).

The Topsham location was chosen for the ASC because CMHC already has a footprint in the region for physician services in the specialties that that will be offered at the Topsham ASC. While patients can receive these services in the Brunswick market, patients lack an in-market, low cost option for the services that would be available at the Topsham ASC. For these Maine residents, their only current options are in higher-cost settings. The proposed ASC would allow patients access to an option that is safe, better aligned with national trends, less costly, and, as part of an integrated health care delivery system, can allow for care coordination to address all of a patient's health care needs. The project will not result in an inappropriate increase in service utilization. To the contrary, the Topsham ASC project has been carefully planned and tailored to meet projected organic growth and provide patients in the community with additional treatment options for local, high quality, effective outpatient surgical services in a cost-effective setting.

B. CONU Discussion

i. CON Standard

The relevant standard for inclusion in this section are specific to the determination that the project does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum as established in Title 24-A, section 6951, when the principles adopted by the Maine Quality Forum are directly applicable to the application.

ii. CON Analysis

This project adds significant additional multi-specialty surgical capacity to a service area that already provides these services. This project proposes 2 OR's and 4 procedure rooms at a cost of approximately $16.5 million. Existing research suggests that when an ASC was added to a market previously without one, rates of outpatient surgery rise.

The applicant suggests that this growth in outpatient surgery would be the result of pent up demand or inadequate capacity. CONU believes that in this small service area with multiple choices for surgical services there may be a danger of induced demand to achieve positive profit margins.

Directly Affected Party Comments:

Perversely, even as the people of Southern Midcoast Maine lose certain services, they'll have an excess of other services, leading to a needless increase in service utilization. Already, CMHC is marketing its proposal heavily in the community, and the experience at the Spectrum surgical center, where CMHC is part owner, is any guide, this surgical center will focus on patients with commercial insurance. It would also push many procedures that are now done safely and comfortably in doctor's offices into its four procedure rooms so as to keep volumes up in a market with insufficient demand to support an over build infrastructure for surgeries and procedures.

Post Technical Assistance Meeting Additional Information – Service Utilization

Project does Not Increase Inappropriate Service Utilization

The proposed ASC will not result in inappropriate increases in service utilization. As outlined in the foregoing Fit, Willing and Able section, ASCs treat only patients who have already seen a health care provider who ordered outpatient surgery as the appropriate treatment for the patient's particular condition.

MaineHealth cited a study that articulated potential utilization increases as ASCs enter a community. However, what was omitted was the study's conclusion that "one plausible explanation [for growth] is that these new facilities are responding to unmet clinical need, either due to inadequate capacity for outpatient surgery or growing patient demand." This is the case with this Project--the Topsham ASC is responding to the inadequate capacity of existing facilities to address the growing patient, employer and community demand for low-cost, high quality surgical services in the southern mid-coast region.

CONU Response to Post Technical Assistance Meeting Additional Information:

CONU believes that in this small service area with multiple choices for surgical services there may be a danger of induced demand to achieve positive profit margins. The proposed services to be provided by the applicant, including urology, ENT, breast care, surgery, gastroenterology and orthopedics are readily available in the proposed service area. Contradictory evidence has been submitted by the applicants and the directly affected party. Without a thorough market analysis and capacity analysis of the service area there is a potential for excess utilization as well as the possibility that there is not enough demand in the area for these proposed new services.

iii. Conclusion

CONU recommends that the Commissioner find that the applicant has **NOT** met their burden to demonstrate that the project does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum.

VIII. Timeline Criteria

Letter of Intent filed	May 8, 2020
Technical Assistance Meeting held on	May 15, 2020
CON Application filed	May 22, 2020
CON Application certified as complete	May 22, 2020
Public Informational Meeting	N/A
Public Hearing held	July 22, 2020
Record closed for comments	August 21, 2020
2nd Technical Assistance Meeting	February 5, 2021

IX. CON Findings and Recommendations

Based on the preceding analysis, including information contained in the record, the CONU recommends that the Commissioner make the following findings and recommendations:

A. That the applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards.

B. The economic feasibility of the proposed services is **NOT** demonstrated in terms of the:

1. Capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expects to be able to charge for the services to be provided by the project; and

2. The applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules;

C. The applicant has **NOT** demonstrated that there is a public need for the proposed services as demonstrated by certain factors, including, but not limited to;

1. The extent to which the project will substantially address specific health problems as measured by health needs in the area to be served by the project;

2. The project has demonstrated that it will have a positive impact on the health status indicators of the population to be served;

3. The project will be accessible to all residents of the area proposed to be served; and

4. The project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project;

D. The applicant has **NOT** demonstrated that the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State as demonstrated by:

1. The impact of the project on total health care expenditures after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;

2. The availability of State funds to cover any increase in state costs associated with utilization of the project's services; and

3. The likelihood that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available was demonstrated by the applicant;

E. The applicant has **NOT** demonstrated that the project ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers; and

F. The applicant has **NOT** demonstrated that the project does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum.

For all the reasons contained in this preliminary analysis and based upon information contained in the record, CONU recommends that the Commissioner determine that this project should be **Denied.**